



Clinical trial results:

A Multicenter, Long-Term Extension to Evaluate the Long Term Safety and Maintenance of Treatment Effect of Mirikizumab in Patients with Moderate to Severe Plaque Psoriasis

Summary

| | |
|--------------------------|-------------------------|
| EudraCT number | 2017-003299-30 |
| Trial protocol | DE CZ HU PL FR GB ES IT |
| Global end of trial date | 07 February 2022 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 22 February 2023 |
| First version publication date | 22 February 2023 |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | I6T-MC-AMAH |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|---------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03556202 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Trial Number: 16491 |

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 07 February 2022 |
| Is this the analysis of the primary completion data? | No |

| | |
|----------------------------------|------------------|
| Global end of trial reached? | Yes |
| Global end of trial date | 07 February 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the long-term safety and maintenance of efficacy of mirikizumab in participants with moderate-to-severe plaque psoriasis.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 03 September 2018 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Argentina: 85 |
| Country: Number of subjects enrolled | Australia: 56 |
| Country: Number of subjects enrolled | Canada: 94 |
| Country: Number of subjects enrolled | Czechia: 88 |
| Country: Number of subjects enrolled | France: 53 |
| Country: Number of subjects enrolled | Germany: 243 |
| Country: Number of subjects enrolled | Hungary: 70 |
| Country: Number of subjects enrolled | Israel: 42 |
| Country: Number of subjects enrolled | Italy: 17 |
| Country: Number of subjects enrolled | Japan: 162 |
| Country: Number of subjects enrolled | Mexico: 71 |
| Country: Number of subjects enrolled | Poland: 279 |
| Country: Number of subjects enrolled | Russian Federation: 46 |
| Country: Number of subjects enrolled | Korea, Republic of: 105 |
| Country: Number of subjects enrolled | Spain: 70 |
| Country: Number of subjects enrolled | Taiwan: 53 |
| Country: Number of subjects enrolled | United Kingdom: 5 |
| Country: Number of subjects enrolled | United States: 397 |
| Worldwide total number of subjects | 1936 |
| EEA total number of subjects | 820 |

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) | 1730 |
| From 65 to 84 years | 205 |
| 85 years and over | 1 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants who completed an originating study: I6T-MC-AMAF (NCT02899988), I6T-MC-AMAK (NCT03482011) and I6T-MC-AMAJ (NCT03535194) were eligible for enrollment into study AMAH.

Period 1

| | |
|------------------------------|-----------------------------|
| Period 1 title | Extension Treatment Period |
| Is this the baseline period? | Yes |
| Allocation method | Non-randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

Initially double-blind (until original, pivotal studies AMAK [NCT03482011] and AMAJ [NCT03535194] are locked and unblinded), then open-label.

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|------------------------------------|
| Arm title | 125 milligram (mg) Mirikizumab Q8W |
|------------------|------------------------------------|

Arm description:

Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W).

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | LY3074828 |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants received 125 mg mirikizumab administered SC Q8W.

| | |
|------------------|--|
| Arm title | 250 mg Mirikizumab Q8W Excluding Secukinumab |
|------------------|--|

Arm description:

Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | LY3074828 |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).

| | |
|------------------|------------------------------------|
| Arm title | Secukinumab/250 mg Mirikizumab Q8W |
|------------------|------------------------------------|

Arm description:

Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.

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

| | |
|--|--|
| Investigational medicinal product name | Mirikizumab |
| Investigational medicinal product code | LY3074828 |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.

| Number of subjects in period 1 | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W |
|--|------------------------------------|--|------------------------------------|
| | | | |
| Started | 527 | 1020 | 389 |
| Received at Least One Dose of Study Drug | 527 | 1020 | 389 |
| From AMAF | 35 | 132 | 0 |
| From AMAK | 83 | 390 | 0 |
| From AMAJ | 409 | 498 | 389 |
| Completed | 0 | 0 | 0 |
| Not completed | 527 | 1020 | 389 |
| Adverse event, serious fatal | 2 | 6 | - |
| Consent withdrawn by subject | 22 | 47 | 22 |
| Physician decision | - | 8 | 2 |
| Adverse event, non-fatal | 18 | 14 | 9 |
| Due to Exclusion Criteria of AMAJ study | - | - | 1 |
| Pregnancy | 2 | 4 | 3 |
| Sponsor Decision | - | 1 | - |
| Study Terminated by Sponsor | 469 | 907 | 331 |
| Lost to follow-up | 9 | 20 | 2 |
| Lack of efficacy | 5 | 12 | 18 |
| Protocol deviation | - | 1 | 1 |

Period 2

| | |
|------------------------------|-----------------------------|
| Period 2 title | Follow-Up Period (12 weeks) |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|----|
| Are arms mutually exclusive? | No |
|------------------------------|----|

| | |
|--|---|
| Arm title | 125 milligram (mg) Mirikizumab Q8W Follow-up Period |
| Arm description: Participants did not receive any intervention in post- treatment follow-up period. | |
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | 250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period |
| Arm description: Participants did not receive any intervention in post- treatment follow-up period. | |
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |
| Arm title | Secukinumab/250 mg Mirikizumab Q8W Follow-up Period |
| Arm description: Participants did not receive any intervention in post- treatment follow-up period. | |
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| Number of subjects in period 2 | 125 milligram (mg) Mirikizumab Q8W Follow-up Period | 250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period | Secukinumab/250 mg Mirikizumab Q8W Follow-up Period |
|--|---|---|---|
| Started | 453 | 861 | 333 |
| Completed | 0 | 0 | 0 |
| Not completed | 453 | 861 | 333 |
| Adverse event, serious fatal | 1 | - | - |
| Physician decision | - | 3 | 1 |
| To meet exclusion criteria of the AMAJ study | - | - | 1 |
| Site Terminated by Sponsor | - | 1 | - |
| Study Terminated by Sponsor | 396 | 750 | 273 |
| Second follow-up not done, unable to reach patient | - | - | 1 |
| Study discontinued by sponsor | - | 2 | 1 |
| Study terminated & subject missed follow-up visit | - | 1 | - |
| Second follow-up visit: Patient refused | - | 1 | - |
| Consent withdrawn by subject | 36 | 65 | 31 |
| Adverse event, non-fatal | 11 | 11 | 8 |
| Pregnancy | 1 | 4 | 1 |
| Lost to follow-up | 4 | 14 | 3 |
| Lack of efficacy | 4 | 9 | 13 |

Baseline characteristics

Reporting groups

| | |
|---|--|
| Reporting group title | 125 milligram (mg) Mirikizumab Q8W |
| Reporting group description: | |
| Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W). | |
| Reporting group title | 250 mg Mirikizumab Q8W Excluding Secukinumab |
| Reporting group description: | |
| Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ). | |
| Reporting group title | Secukinumab/250 mg Mirikizumab Q8W |
| Reporting group description: | |
| Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W. | |

| Reporting group values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W |
|------------------------|------------------------------------|--|------------------------------------|
| Number of subjects | 527 | 1020 | 389 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|---|---------|---------|---------|
| Age continuous | | | |
| All randomized participants. | | | |
| Units: years | | | |
| arithmetic mean | 47.90 | 47.00 | 46.50 |
| standard deviation | ± 13.81 | ± 12.87 | ± 14.41 |
| Gender categorical | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Female | 159 | 309 | 110 |
| Male | 368 | 711 | 279 |
| Ethnicity (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 29 | 63 | 20 |
| Not Hispanic or Latino | 79 | 150 | 53 |
| Unknown or Not Reported | 419 | 807 | 316 |
| Race (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 15 | 48 | 2 |
| Asian | 89 | 217 | 63 |
| Native Hawaiian or Other Pacific Islander | 1 | 1 | 1 |
| Black or African American | 5 | 18 | 6 |
| White | 415 | 734 | 315 |
| More than one race | 2 | 2 | 2 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Region of Enrollment | | | |

| | | | |
|------------------------------|-----|-----|----|
| All randomized participants. | | | |
| Units: Subjects | | | |
| Argentina | 32 | 30 | 23 |
| Australia | 16 | 21 | 19 |
| Canada | 26 | 44 | 24 |
| Czechia | 25 | 35 | 28 |
| France | 20 | 15 | 18 |
| Germany | 65 | 136 | 42 |
| Hungary | 23 | 27 | 20 |
| Israel | 12 | 15 | 15 |
| Italy | 7 | 5 | 5 |
| Japan | 39 | 86 | 37 |
| Mexico | 15 | 56 | 0 |
| Poland | 75 | 157 | 47 |
| Russia | 3 | 43 | 0 |
| South Korea | 24 | 68 | 13 |
| Spain | 24 | 22 | 24 |
| Taiwan | 9 | 44 | 0 |
| United Kingdom | 2 | 2 | 1 |
| United States | 110 | 214 | 73 |

| | | | |
|-------------------------------|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 1936 | | |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|---|------|--|--|
| Age continuous | | | |
| All randomized participants. | | | |
| Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |
| Gender categorical | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Female | 578 | | |
| Male | 1358 | | |
| Ethnicity (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 112 | | |
| Not Hispanic or Latino | 282 | | |
| Unknown or Not Reported | 1542 | | |
| Race (NIH/OMB) | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 65 | | |
| Asian | 369 | | |
| Native Hawaiian or Other Pacific Islander | 3 | | |
| Black or African American | 29 | | |
| White | 1464 | | |
| More than one race | 6 | | |

| | | | |
|------------------------------|-----|--|--|
| Unknown or Not Reported | 0 | | |
| Region of Enrollment | | | |
| All randomized participants. | | | |
| Units: Subjects | | | |
| Argentina | 85 | | |
| Australia | 56 | | |
| Canada | 94 | | |
| Czechia | 88 | | |
| France | 53 | | |
| Germany | 243 | | |
| Hungary | 70 | | |
| Israel | 42 | | |
| Italy | 17 | | |
| Japan | 162 | | |
| Mexico | 71 | | |
| Poland | 279 | | |
| Russia | 46 | | |
| South Korea | 105 | | |
| Spain | 70 | | |
| Taiwan | 53 | | |
| United Kingdom | 5 | | |
| United States | 397 | | |

End points

End points reporting groups

| | |
|---|---|
| Reporting group title | 125 milligram (mg) Mirikizumab Q8W |
| Reporting group description: Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W). | |
| Reporting group title | 250 mg Mirikizumab Q8W Excluding Secukinumab |
| Reporting group description: Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ). | |
| Reporting group title | Secukinumab/250 mg Mirikizumab Q8W |
| Reporting group description: Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W. | |
| Reporting group title | 125 milligram (mg) Mirikizumab Q8W Follow-up Period |
| Reporting group description: Participants did not receive any intervention in post- treatment follow-up period. | |
| Reporting group title | 250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period |
| Reporting group description: Participants did not receive any intervention in post- treatment follow-up period. | |
| Reporting group title | Secukinumab/250 mg Mirikizumab Q8W Follow-up Period |
| Reporting group description: Participants did not receive any intervention in post- treatment follow-up period. | |

Primary: Percentage of Participants with a Static Physician's Global Assessment Among Those who Entered the Study with a sPGA of 0,1

| | |
|--|--|
| End point title | Percentage of Participants with a Static Physician's Global Assessment Among Those who Entered the Study with a sPGA of 0,1 ^[1] |
| End point description: The sPGA is the physician's determination of the participant's psoriasis (PsO) lesions overall at a given time point. Lesions were categorized by descriptions for induration, erythema, and scaling. Participant's PsO was assessed as 0 (clear), 1 (minimal), 2 (mild), 3 (moderate), 4 (severe), or 5 (very severe). An sPGA responder was defined as having a post-baseline sPGA score of "0" or "1" with at least a 2-point improvement from baseline. Participants who did not meet the clinical response criteria or had missing data at Week 104 were considered non-responders for non-responder Imputation (NRI) analysis. Analysis population description (APD): All randomized participants who received at least one dose of drug and who entered Study AMAH with sPGA (0,1). | |
| End point type | Primary |
| End point timeframe: Week 104 | |
| 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 inferential statistics was planned/conducted for this endpoint. | |

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/2 50 mg Mirikizumab Q8W | |
|-----------------------------------|------------------------------------|--|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 467 | 820 | 296 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 46.7 (42.2 to 51.2) | 55.7 (52.3 to 59.1) | 38.9 (33.3 to 44.4) | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants who Maintained a $\geq 90\%$ Improvements in Psoriasis Area and Severity Index (PASI) 90 Among Those who Entered the Study with a PASI 90

| | |
|-----------------|---|
| End point title | Percentage of Participants who Maintained a $\geq 90\%$ Improvements in Psoriasis Area and Severity Index (PASI) 90 Among Those who Entered the Study with a PASI 90 ^[2] |
|-----------------|---|

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease). APD: All randomized participants who received at least one dose of drug and who entered AMAH with PASI 90 Response.

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

End point timeframe:

Week 104

Notes:

[2] - 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 inferential statistics was planned/conducted for this endpoint.

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/2 50 mg Mirikizumab Q8W | |
|-----------------------------------|------------------------------------|--|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 460 | 813 | 302 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 49.3 (44.8 to 53.9) | 56.8 (53.4 to 60.2) | 39.4 (33.9 to 44.9) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a 100% Improvement in Psoriasis Area and Severity Index (PASI 100)

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving a 100% Improvement in Psoriasis Area and Severity Index (PASI 100) |
|-----------------|---|

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs) and the severity of scaling, redness, and plaque induration/infiltration (thickness) in each region. For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (no involvement) to 4 (severe involvement). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor [head (0.1), upper limbs (0.2), trunk (0.3), lower limbs (0.4)]. Overall scores range from 0 (no PsO) to 72 (the most severe disease). APD: All randomized participants who received at least one dose of drug.

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

End point timeframe:

Week 104

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/2 50 mg Mirikizumab Q8W | |
|-----------------------------------|------------------------------------|--|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 527 | 1020 | 389 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 30.4 (26.4 to 34.3) | 36.4 (33.4 to 39.3) | 22.6 (18.5 to 26.8) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptom Score of 0 (free of itch, pain, stinging, and burning) in Those with a PSS Symptoms Score ≥ 1 at Baseline

| | |
|-----------------|---|
| End point title | Percentage of Participants with a Psoriasis Symptoms Scale (PSS) Symptom Score of 0 (free of itch, pain, stinging, and burning) in Those with a PSS Symptoms Score ≥ 1 at Baseline |
|-----------------|---|

End point description:

PSS is a patient-administered assessment of 4 symptoms (itch, pain, stinging, and burning); 3 signs (redness, scaling, and cracking); and 1 item on the discomfort related to symptoms/signs. The overall severity for each individual symptom/sign from the patient's psoriasis is indicated by selecting the number from a numeric rating scale (NRS) of 0 to 10 that best describes the worst level of each symptom/sign in the past 24 hours, where 0=no symptom/sign and 10=worst imaginable symptom/sign. In addition, a symptoms score ranging from 0 (no symptoms) to 40 (worst imaginable symptoms), and sign score of 0 (no signs) to 30 (worst imaginable signs) will be reported. APD: All randomized participants with PSS symptom score of ≥ 1 at baseline.

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

End point timeframe:

Week 104

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W | |
|-----------------------------------|------------------------------------|--|------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 518 | 1008 | 376 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 31.1 (27.1 to 35.1) | 33.6 (30.7 to 36.5) | 23.4 (19.1 to 27.7) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Total Score of (0,1) With at Least a 5-Point Improvement (Reduction) From Baseline in Participants With a Baseline DLQI Total Score ≥ 5

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) Total Score of (0,1) With at Least a 5-Point Improvement (Reduction) From Baseline in Participants With a Baseline DLQI Total Score ≥ 5 |
|-----------------|---|

End point description:

The DLQI is a patient-reported, 10-question, quality-of-life questionnaire that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Response categories include "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. Questions 3-10 also have an additional response category of "Not relevant" which is scored as "0". For all questions, if unanswered the question is scored as "0". Totals range from 0 to 30 (less to more impairment). A DLQI total score of 0 to 1 is considered as having no effect on a patient's health-related quality of life (HRQoL), and a 5-point change from baseline is considered as the minimal clinically important difference (MCID) threshold. APD: All randomized participants who had a baseline DLQI Total Score ≥ 5 .

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

End point timeframe:

Week 104

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W | |
|-----------------------------------|------------------------------------|--|------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 477 | 922 | 345 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 41.5 (37.1 to 45.9) | 47.3 (44.1 to 50.5) | 34.5 (29.5 to 39.5) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Psoriasis Scalp Severity Index (PSSI) Total Score in Participants with Scalp Involvement at Baseline

| | |
|-----------------|--|
| End point title | Change in Psoriasis Scalp Severity Index (PSSI) Total Score in Participants with Scalp Involvement at Baseline |
|-----------------|--|

End point description:

The PSSI is a physician assessment of erythema, induration and desquamation and percent of scalp that is covered with a scores range from 0 (none) to 4 (very severe). The composite score is derived from the sum of scores for erythema, induration, and desquamation multiplied by the score recorded for the extent of the scalp area involved, 1 (<10%) to 6 (90%-100%) with a total score ranging from 0 (less severity) to 72 (more severity). APD: All randomized participants who had Scalp Involvement at baseline.

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

End point timeframe:

Baseline, Week 104

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W | |
|--------------------------------------|------------------------------------|--|------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 204 | 454 | 136 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | -20.9 (± 15.79) | -19.5 (± 13.48) | -19.6 (± 13.44) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Nail Psoriasis Severity Index (NAPSI) Total Score in Participants with Fingernail Involvement at Baseline

| | |
|-----------------|---|
| End point title | Change in Nail Psoriasis Severity Index (NAPSI) Total Score in Participants with Fingernail Involvement at Baseline |
|-----------------|---|

End point description:

The NAPSI scale is used to evaluate the severity of fingernail bed Ps and fingernail matrix PsO by area of involvement. The fingernail is divided into quadrants. Each fingernail is given a score for fingernail bed PsO 0 (none) to 4 (PsO in 4 quadrants of the fingernail) and fingernail matrix PsO 0 (none) to 4 (Ps in 4 quadrants of the matrix), depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed or matrix PsO in each quadrant. The sum of all fingernails equals the total NAPSI score range is from 0 (no effect) to 80 (more severe psoriasis). APD: All randomized participants who had Nail Psoriasis involvement at baseline.

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

End point timeframe:

Baseline, Week 104

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/2 50 mg Mirikizumab Q8W | |
|--------------------------------------|------------------------------------|--|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 136 | 304 | 89 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | -19.4 (± 17.75) | -21.0 (± 17.69) | -22.2 (± 18.75) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change in Palmoplantar Psoriasis Severity Index (PPASI) Total Score in Participants With Palmoplantar Involvement at Baseline

| | |
|-----------------|---|
| End point title | Change in Palmoplantar Psoriasis Severity Index (PPASI) Total Score in Participants With Palmoplantar Involvement at Baseline |
|-----------------|---|

End point description:

The PPASI is a composite score derived from the sum scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement, ranging from 0 (no PPASI) to 72 (most severe PPASI). The PPASI was only assessed if participants have palmoplantar psoriasis at baseline. APD: All randomized participants who had palmoplantar involvement at baseline.

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

End point timeframe:

Baseline, Week 104

| End point values | 125 milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/2 50 mg Mirikizumab Q8W | |
|--------------------------------------|------------------------------------|--|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 51 | 114 | 31 | |
| Units: score on a scale | | | | |
| arithmetic mean (standard deviation) | -6.55 (± 7.058) | -6.80 (± 8.391) | -7.38 (± 6.632) | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment Period: Baseline Up To 208 Weeks, Follow-up Period: 0-12 Weeks

Adverse event reporting additional description:

All participants who received at least one dose of drug. Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 24.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------------------------|
| Reporting group title | 125 Milligram (mg) Mirikizumab Q8W |
|-----------------------|------------------------------------|

Reporting group description:

Participants received 125 mg mirikizumab administered subcutaneously (SC) every eight weeks (Q8W).

| | |
|-----------------------|--|
| Reporting group title | 250 mg Mirikizumab Q8W Excluding Secukinumab |
|-----------------------|--|

Reporting group description:

Participants received 250 mg mirikizumab administered SC Q8W excluding participants who received secukinumab of their originating study (AMAJ).

| | |
|-----------------------|------------------------------------|
| Reporting group title | Secukinumab/250 mg Mirikizumab Q8W |
|-----------------------|------------------------------------|

Reporting group description:

Participants from previous originating study [who received secukinumab (AMAJ)] received 250 mg mirikizumab administered SC Q8W.

| | |
|-----------------------|---|
| Reporting group title | 125 Milligram (mg) Mirikizumab Q8W Follow-up Period |
|-----------------------|---|

Reporting group description:

Participants did not receive any intervention in post- treatment follow-up period.

| | |
|-----------------------|---|
| Reporting group title | 250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period |
|-----------------------|---|

Reporting group description:

Participants did not receive any intervention in post- treatment follow-up period.

| | |
|-----------------------|---|
| Reporting group title | Secukinumab/250 mg Mirikizumab Q8W Follow-up Period |
|-----------------------|---|

Reporting group description:

Participants did not receive any intervention in post- treatment follow-up period.

| Serious adverse events | 125 Milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W |
|---|------------------------------------|--|------------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 55 / 527 (10.44%) | 88 / 1020 (8.63%) | 35 / 389 (9.00%) |
| number of deaths (all causes) | 2 | 6 | 0 |
| number of deaths resulting from adverse events | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| acute myeloid leukaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| adenocarcinoma of colon alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| b-cell lymphoma alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast cancer alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| colon cancer metastatic alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| gastric cancer alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| glioblastoma alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| growth hormone-producing pituitary tumour | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemangioma of bone | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| invasive lobular breast carcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| lipoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung adenocarcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| marginal zone lymphoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myelodysplastic syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-small cell lung cancer stage iii alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| prostate cancer recurrent alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[1] | 0 / 368 (0.00%) | 0 / 711 (0.00%) | 1 / 279 (0.36%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sinonasal papilloma alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| squamous cell carcinoma of the oral cavity alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| superficial spreading melanoma stage unspecified alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| thyroid cancer alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| Vascular disorders | | | |
| aortic aneurysm rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deep vein thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| embolism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| varicose vein | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vasculitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| blepharoplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| cholecystectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| coronary revascularisation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric polypectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hysterectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[2] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (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 |
| percutaneous coronary intervention | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral revascularisation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| stent placement | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| stent removal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| General disorders and administration site conditions | | | |
| asthenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| death | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| gait disturbance | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| oedema peripheral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| corneal graft rejection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 | | | |
| acquired phimosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[3] | 0 / 368 (0.00%) | 1 / 711 (0.14%) | 0 / 279 (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 |
| endometriosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed ^[4] | 0 / 159 (0.00%) | 0 / 309 (0.00%) | 1 / 110 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| genital haemorrhage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| haemorrhagic ovarian cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[5] | 0 / 159 (0.00%) | 0 / 309 (0.00%) | 1 / 110 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| uterine polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[6] | 0 / 159 (0.00%) | 0 / 309 (0.00%) | 1 / 110 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| asthma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| asthmatic crisis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| dyspnoea exertional | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| hypercapnia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 embolism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| sleep apnoea syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| alcohol withdrawal syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| depression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| mental status changes | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| Product issues | | | |
| device dislocation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 | | | |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| Injury, poisoning and procedural complications | | | |
| animal bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| cervical vertebral fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clavicle fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (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 |
| closed globe injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| concussion alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| face injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| facial bones fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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| femoral neck fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| foot fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| graft complication | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| hip fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| joint dislocation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ligament sprain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| limb injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| limb traumatic amputation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| lower limb fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lumbar vertebral fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meniscus injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| muscle injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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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| neovaginal complication | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[7] | 0 / 159 (0.00%) | 0 / 309 (0.00%) | 1 / 110 (0.91%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural complication | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| 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 contusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| radius fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| scapula fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skull fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 compression fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| tendon injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tendon rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| Congenital, familial and genetic disorders | | | |
| odontogenic cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 disorders | | | |
| acute coronary syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| acute myocardial infarction alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 3 / 389 (0.77%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina unstable alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| atrial fibrillation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure congestive alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| cardiogenic shock alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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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| coronary artery disease alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| coronary artery stenosis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| myocardial infarction alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| myocardial ischaemia alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pericarditis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| ventricular tachycardia alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| Nervous system disorders carotid artery stenosis alternative dictionary used: MedDRA 24.1 | | | |

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|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral arteriosclerosis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral venous sinus thrombosis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebrovascular accident alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic inflammatory demyelinating polyradiculoneuropathy alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| essential tremor alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| haemorrhage intracranial alternative dictionary used: MedDRA 24.1 | | | |

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|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| headache | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| ischaemic stroke | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| sedation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| transient ischaemic attack | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| sudden hearing loss | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| vertigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| Eye disorders | | | |
| cataract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| keratitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| ocular hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| optic neuropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| colitis ulcerative | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric haemorrhage alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastritis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestine polyp alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis acute alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| Hepatobiliary disorders cholecystitis alternative dictionary used: MedDRA 24.1 | | | |

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|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis acute alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis chronic alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| cholelithiasis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| gallbladder fistula alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| Skin and subcutaneous tissue disorders | | | |
| dermatitis contact alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| drug eruption alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| ureterolithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| primary hyperaldosteronism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| flank pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| intervertebral disc disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (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 |
| osteoarthritis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| rotator cuff syndrome alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| Infections and infestations | | | |
| abscess limb alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| acute sinusitis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| appendicitis alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| bacteraemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| covid-19 pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 8 / 1020 (0.78%) | 2 / 389 (0.51%) |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 8 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| campylobacter colitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |

| | | | |
|--|-----------------|------------------|-----------------|
| campylobacter gastroenteritis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| cellulitis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic tonsillitis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulitis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| enterocolitis viral alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (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 |
| escherichia pyelonephritis alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| localised infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (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 |
| neutropenic sepsis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| osteomyelitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pneumonia bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (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 |
| post procedural infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------------------------|------------------------------------|-----------------------------------|
| postoperative wound infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 527 (0.19%) 0 / 1 0 / 0 | 0 / 1020 (0.00%) 0 / 0 0 / 0 | 0 / 389 (0.00%) 0 / 0 0 / 0 |
| scrotal abscess alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[8] occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 368 (0.00%) 0 / 0 0 / 0 | 1 / 711 (0.14%) 1 / 1 0 / 0 | 0 / 279 (0.00%) 0 / 0 0 / 0 |
| sinusitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 527 (0.00%) 0 / 0 0 / 0 | 0 / 1020 (0.00%) 0 / 0 0 / 0 | 1 / 389 (0.26%) 0 / 1 0 / 0 |
| soft tissue infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 527 (0.00%) 0 / 0 0 / 0 | 1 / 1020 (0.10%) 0 / 1 0 / 0 | 0 / 389 (0.00%) 0 / 0 0 / 0 |
| Metabolism and nutrition disorders diabetes mellitus alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 527 (0.00%) 0 / 0 0 / 0 | 0 / 1020 (0.00%) 0 / 0 0 / 0 | 1 / 389 (0.26%) 1 / 1 0 / 0 |
| shock hypoglycaemic alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 527 (0.19%) 0 / 1 0 / 0 | 0 / 1020 (0.00%) 0 / 0 0 / 0 | 0 / 389 (0.00%) 0 / 0 0 / 0 |

| | | | |
|-------------------------------|---|--|--|
| Serious adverse events | 125 Milligram (mg) Mirikizumab Q8W Follow-up Period | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W Follow-up |
|-------------------------------|---|--|--|

| | | Follow-up Period | Period |
|---|-----------------|------------------|-----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 453 (1.55%) | 6 / 861 (0.70%) | 0 / 333 (0.00%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| acute myeloid leukaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| adenocarcinoma of colon | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| b-cell lymphoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| breast cancer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| colon cancer metastatic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric cancer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| glioblastoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| growth hormone-producing pituitary tumour | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemangioma of bone | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| invasive lobular breast carcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lipoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lung adenocarcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| marginal zone lymphoma alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myelodysplastic syndrome alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| non-small cell lung cancer stage iii alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| prostate cancer recurrent alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[1] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sinonasal papilloma alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 the oral cavity alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| superficial spreading melanoma stage unspecified | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| thyroid cancer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| aortic aneurysm rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deep vein thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| embolism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral arterial occlusive disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| varicose vein | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vasculitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| blepharoplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary revascularisation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric polypectomy alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (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 |
| hysterectomy alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[2] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| percutaneous coronary intervention alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| peripheral revascularisation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (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 |
| stent placement alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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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| stent removal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| asthenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| death | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gait disturbance | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| oedema peripheral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (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 |
| Immune system disorders | | | |
| corneal graft rejection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |

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|--|-----------------|-----------------|-----------------|
| acquired phimosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[3] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| endometriosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[4] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| genital haemorrhage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 ovarian cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[5] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| 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 polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[6] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| asthma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| asthmatic crisis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| dyspnoea exertional | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hypercapnia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary embolism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| respiratory failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sleep apnoea syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| alcohol withdrawal syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| depression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Product issues | | | |
| device dislocation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| animal bite | | | |

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| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cervical vertebral fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| clavicle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| closed globe injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| concussion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| face injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| facial bones fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| femoral neck fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| foot fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| graft complication alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hand fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| hip fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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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| joint dislocation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ligament sprain alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| limb injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| limb traumatic amputation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lower limb fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| lumbar vertebral fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| meniscus injury alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| muscle injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| neovaginal complication | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[7] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural complication | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pulmonary contusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| radius fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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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| road traffic accident alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| scapula fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| skull fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| spinal compression fracture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| tendon injury alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (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 |
| tendon rupture alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders odontogenic cyst alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 coronary syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| acute myocardial infarction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiac failure congestive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cardiogenic shock | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| coronary artery stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| myocardial infarction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (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 |
| myocardial ischaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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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| ventricular tachycardia alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| carotid artery stenosis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral arteriosclerosis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cerebral venous sinus thrombosis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (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 |
| cerebrovascular accident alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic inflammatory demyelinating polyradiculoneuropathy alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| essential tremor alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| haemorrhage intracranial alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| headache alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ischaemic stroke alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sedation alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| transient ischaemic attack alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 sudden hearing loss alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| vertigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| cataract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| keratitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ocular hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| optic neuropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 | | | |
| colitis ulcerative | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (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 |
| diverticulum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric haemorrhage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| gastric ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (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 |
| gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| pancreatitis acute | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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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| Hepatobiliary disorders | | | |
| cholecystitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis acute | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholecystitis chronic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (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 |
| gallbladder fistula | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| dermatitis contact | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| drug eruption | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (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 |
| urticaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ureterolithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| primary hyperaldosteronism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| flank pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| intervertebral disc protrusion alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteoarthritis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| rotator cuff syndrome alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| abscess limb alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| acute sinusitis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (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 |
| covid-19 pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| campylobacter colitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| campylobacter gastroenteritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| cellulitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| chronic tonsillitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| diverticulitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| enterocolitis viral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 pyelonephritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| localised infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| neutropenic sepsis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| osteomyelitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| 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 bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| post procedural infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (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 |

| | | | |
|--|-----------------|-----------------|-----------------|
| postoperative wound infection alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| scrotal abscess alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[8] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| sinusitis alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| soft tissue infection alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| diabetes mellitus alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| shock hypoglycaemic alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Notes:

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

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[2] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[3] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[4] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[5] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[6] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[7] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[8] - 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: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | 125 Milligram (mg) Mirikizumab Q8W | 250 mg Mirikizumab Q8W Excluding Secukinumab | Secukinumab/250 mg Mirikizumab Q8W |
|--|---------------------------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 388 / 527 (73.62%) | 756 / 1020 (74.12%) | 288 / 389 (74.04%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) acrochordon alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 2 / 1020 (0.20%) 2 | 1 / 389 (0.26%) 1 |
| adenoma benign alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| anogenital warts alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| basal cell carcinoma | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 1 | 1 |
| benign breast neoplasm | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| benign hepatobiliary neoplasm | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| benign neoplasm of thyroid gland | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| benign vascular neoplasm | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| bowen's disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| colon adenoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| dysplastic naevus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 2 | 3 |
| fibroma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| fibrous histiocytoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| focal nodular hyperplasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haemangioma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| lentigo maligna | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| lipoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| malignant ascites | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| melanocytic naevus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 4 | 1 |
| meningioma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| neoplasm malignant | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pituitary tumour benign | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| prostate cancer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[9] | 0 / 368 (0.00%) | 1 / 711 (0.14%) | 0 / 279 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pyogenic granuloma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| seborrhoeic keratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 6 / 1020 (0.59%) | 4 / 389 (1.03%) |
| occurrences (all) | 1 | 7 | 4 |
| squamous cell carcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| uterine leiomyoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[10] | 3 / 159 (1.89%) | 4 / 309 (1.29%) | 0 / 110 (0.00%) |
| occurrences (all) | 3 | 4 | 0 |
| Vascular disorders | | | |

| | | | |
|---|------------------|-------------------|------------------|
| aortic thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| arteriosclerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| deep vein thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| essential hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| flushing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| hot flush | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 22 / 527 (4.17%) | 52 / 1020 (5.10%) | 14 / 389 (3.60%) |
| occurrences (all) | 22 | 54 | 15 |
| hypertensive crisis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 3 | 2 | 1 |
| hypotension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| jugular vein thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lymphoedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| lymphorrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| orthostatic hypotension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| peripheral artery occlusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| peripheral venous disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| phlebitis superficial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|----------------------|-----------------------|----------------------|
| post thrombotic syndrome alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| thrombosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| varicose vein alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 2 / 527 (0.38%) 5 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| white coat hypertension alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 2 / 1020 (0.20%) 2 | 0 / 389 (0.00%) 0 |
| Surgical and medical procedures abscess drainage alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| acrochordon excision alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| ankle operation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| appendicectomy alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| cardiac ablation alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| cardioversion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| carpal tunnel decompression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 4 | 1 |
| cataract operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 1 | 2 |
| cholecystectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| circumcision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[11] | 0 / 368 (0.00%) | 1 / 711 (0.14%) | 0 / 279 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| corneal transplant | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| coronary revascularisation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| dental care | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| dental implantation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| endodontic procedure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| endoscopic sleeve gastroplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| eyelid cyst removal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| finger amputation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| gastric bypass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| hernia hiatus repair | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hernia repair | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hysterectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed ^[12] | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| internal fixation of fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| intra-uterine contraceptive device insertion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[13] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| intraocular lens implant | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| knee arthroplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| knee operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| laparoscopic surgery | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| large intestinal polypectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| lens extraction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| lipolysis procedure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| lipoma excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| lithotripsy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| nasal operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| open reduction of fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| papilloma excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| percutaneous coronary intervention | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 5 / 1020 (0.49%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 6 | 1 |
| peripheral nerve neurostimulation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| phlebectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| polypectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| pterygium operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rhinoplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| sinus operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin neoplasm excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| splint application | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| suture insertion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tenoplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| tonsillectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 7 / 527 (1.33%) | 22 / 1020 (2.16%) | 2 / 389 (0.51%) |
| occurrences (all) | 9 | 23 | 2 |
| tooth restoration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tumour excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| uterine dilation and curettage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[14] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vasectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[15] | 0 / 368 (0.00%) | 1 / 711 (0.14%) | 0 / 279 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vitrectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| wisdom teeth removal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 2 | 1 |
| wound drainage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| adverse drug reaction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 3 |
| asthenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 4 / 389 (1.03%) |
| occurrences (all) | 2 | 1 | 4 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| chest pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| chills | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| effusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| fatigue | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 5 / 527 (0.95%) | 10 / 1020 (0.98%) | 3 / 389 (0.77%) |
| occurrences (all) | 6 | 10 | 3 |
| granuloma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| hyperthermia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| implant site irritation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| influenza like illness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 4 / 1020 (0.39%) | 4 / 389 (1.03%) |
| occurrences (all) | 3 | 5 | 6 |
| injection site discolouration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| injection site bruising | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| injection site erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 8 / 1020 (0.78%) | 3 / 389 (0.77%) |
| occurrences (all) | 2 | 26 | 6 |
| injection site haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 3 |

| | | | |
|--|-----------------------|--------------------------|------------------------|
| injection site induration alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| injection site inflammation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 2 / 389 (0.51%) 3 |
| injection site oedema alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 3 / 1020 (0.29%) 5 | 1 / 389 (0.26%) 2 |
| injection site pain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 8 / 527 (1.52%) 79 | 22 / 1020 (2.16%) 283 | 6 / 389 (1.54%) 36 |
| injection site rash alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| injection site pruritus alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 2 / 1020 (0.20%) 12 | 2 / 389 (0.51%) 3 |
| injection site swelling alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 2 / 1020 (0.20%) 3 | 1 / 389 (0.26%) 1 |
| injection site reaction alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 6 / 527 (1.14%) 15 | 19 / 1020 (1.86%) 108 | 19 / 389 (4.88%) 44 |
| lithiasis alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| malaise | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 1 | 1 |
| mucosal inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| nodule | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| oedema peripheral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 4 | 2 | 1 |
| pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 3 / 389 (0.77%) |
| occurrences (all) | 1 | 1 | 3 |
| peripheral swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 3 | 2 |
| puncture site pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|------------------|-------------------|------------------|
| pyrexia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 11 / 527 (2.09%) | 17 / 1020 (1.67%) | 11 / 389 (2.83%) |
| occurrences (all) | 12 | 17 | 13 |
| swelling face | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| temperature regulation disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tenderness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vaccination site joint pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| vaccination site oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| vaccination site swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vaccination site pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 12 / 1020 (1.18%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 16 | 2 |
| xerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Immune system disorders | | | |
| allergy to animal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| allergy to arthropod bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| allergy to arthropod sting | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| anaphylactic reaction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| drug hypersensitivity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| food allergy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hypersensitivity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| seasonal allergy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 9 / 1020 (0.88%) | 3 / 389 (0.77%) |
| occurrences (all) | 6 | 10 | 3 |
| Reproductive system and breast disorders | | | |
| adenomyosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[16] | 2 / 159 (1.26%) | 0 / 309 (0.00%) | 0 / 110 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| balanoposthitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[17] | 1 / 368 (0.27%) | 1 / 711 (0.14%) | 0 / 279 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[18] | 3 / 368 (0.82%) | 6 / 711 (0.84%) | 2 / 279 (0.72%) |
| occurrences (all) | 3 | 6 | 2 |
| breast calcifications | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| breast cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| breast disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| breast mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| breast pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| cervical cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[19] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[20] | 0 / 159 (0.00%) | 3 / 309 (0.97%) | 1 / 110 (0.91%) |
| occurrences (all) | 0 | 12 | 1 |
| endometrial thickening | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[21] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| endometriosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[22] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 1 / 110 (0.91%) |
| occurrences (all) | 0 | 1 | 1 |
| erectile dysfunction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[23] | 0 / 368 (0.00%) | 1 / 711 (0.14%) | 0 / 279 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| genital erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| genital lesion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| heavy menstrual bleeding | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[24] | 0 / 159 (0.00%) | 0 / 309 (0.00%) | 1 / 110 (0.91%) |
| occurrences (all) | 0 | 0 | 1 |
| intermenstrual bleeding | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[25] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| menopausal symptoms | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[26] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| menstruation irregular | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[27] | 1 / 159 (0.63%) | 0 / 309 (0.00%) | 0 / 110 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[28] | 1 / 159 (0.63%) | 2 / 309 (0.65%) | 2 / 110 (1.82%) |
| occurrences (all) | 1 | 2 | 2 |
| perineal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| perineal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| polycystic ovaries | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[29] | 1 / 159 (0.63%) | 0 / 309 (0.00%) | 0 / 110 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| premenstrual pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed ^[30] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| prostatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[31] | 1 / 368 (0.27%) | 0 / 711 (0.00%) | 0 / 279 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pruritus genital | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| uterine cervical metaplasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[32] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vulval eczema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[33] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vulvovaginal inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[34] | 1 / 159 (0.63%) | 0 / 309 (0.00%) | 0 / 110 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| vulvovaginal pruritus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[35] | 1 / 159 (0.63%) | 0 / 309 (0.00%) | 0 / 110 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| allergic cough | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| allergic pharyngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| asthma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 5 / 1020 (0.49%) | 0 / 389 (0.00%) |
| occurrences (all) | 6 | 5 | 0 |
| atelectasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| bronchitis chronic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| catarrh | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| cough | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 16 / 527 (3.04%) | 28 / 1020 (2.75%) | 8 / 389 (2.06%) |
| occurrences (all) | 16 | 30 | 8 |
| cough variant asthma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| dysphonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| dyspnoea exertional | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| dyspnoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 7 / 1020 (0.69%) | 2 / 389 (0.51%) |
| occurrences (all) | 4 | 8 | 3 |
| epistaxis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 3 / 389 (0.77%) |
| occurrences (all) | 2 | 0 | 3 |
| hiccups | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperventilation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| laryngeal disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lower respiratory tract congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 5 | 4 | 0 |
| nasal oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| nasal septum deviation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| nasal polyps | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| nasal turbinate abnormality | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| nasal turbinate hypertrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| nasal ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oropharyngeal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 11 / 1020 (1.08%) | 6 / 389 (1.54%) |
| occurrences (all) | 5 | 12 | 6 |
| paranasal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| paranasal sinus discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| pleural effusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| productive cough | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| pulmonary hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pulmonary mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| pulmonary oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| rhinitis allergic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 15 / 1020 (1.47%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 17 | 2 |
| rhinorrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 6 / 1020 (0.59%) | 1 / 389 (0.26%) |
| occurrences (all) | 4 | 8 | 1 |
| sinonasal obstruction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| sinus congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 6 | 1 |
| sleep apnoea syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 6 / 1020 (0.59%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 6 | 2 |
| sneezing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| throat irritation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| upper respiratory tract inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| vocal cord leukoplakia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| vocal cord polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| wheezing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| adjustment disorder with depressed mood | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| affective disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| alcohol abuse | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| anxiety | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 11 / 1020 (1.08%) | 7 / 389 (1.80%) |
| occurrences (all) | 7 | 12 | 7 |
| attention deficit hyperactivity disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| confusional state | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| depression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 7 / 527 (1.33%) | 6 / 1020 (0.59%) | 4 / 389 (1.03%) |
| occurrences (all) | 7 | 6 | 4 |
| depressed mood | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| distractibility | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| dysphoria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| initial insomnia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 1 | 3 |
| insomnia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 11 / 1020 (1.08%) | 1 / 389 (0.26%) |
| occurrences (all) | 4 | 11 | 1 |
| major depression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| mental fatigue | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| mental status changes | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| mood swings | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 2 |
| panic attack | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| sleep disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 6 / 1020 (0.59%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 7 | 0 |
| stress | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| suicidal behaviour | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| suicide attempt | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 9 / 527 (1.71%) | 23 / 1020 (2.25%) | 3 / 389 (0.77%) |
| occurrences (all) | 10 | 28 | 3 |
| arthroscopy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 9 / 527 (1.71%) | 15 / 1020 (1.47%) | 0 / 389 (0.00%) |
| occurrences (all) | 11 | 22 | 0 |
| aspiration joint | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| basophil count increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| bilirubin conjugated increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| biopsy lymph gland | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| biopsy skin | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| blood alkaline phosphatase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 5 | 0 |
| blood bilirubin increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| blood cholesterol increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| blood creatine phosphokinase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 10 / 527 (1.90%) | 20 / 1020 (1.96%) | 7 / 389 (1.80%) |
| occurrences (all) | 11 | 25 | 8 |

| | | | |
|--|----------------------|-----------------------|----------------------|
| blood creatinine increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 3 / 1020 (0.29%) 3 | 0 / 389 (0.00%) 0 |
| blood gastrin increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| blood glucose increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 2 / 1020 (0.20%) 2 | 1 / 389 (0.26%) 1 |
| blood iron decreased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 2 / 527 (0.38%) 2 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| blood parathyroid hormone increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| blood potassium increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 1 / 389 (0.26%) 1 |
| blood pressure abnormal alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| blood pressure increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 3 / 527 (0.57%) 4 | 4 / 1020 (0.39%) 6 | 2 / 389 (0.51%) 2 |
| blood testosterone decreased alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| blood thyroid stimulating hormone increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| blood triglycerides increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 9 / 1020 (0.88%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 11 | 2 |
| blood urea increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| blood uric acid increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 3 | 5 | 1 |
| body height decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| body temperature increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| bone scan | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cardiac murmur | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |

| | | | |
|---|-----------------|------------------|-----------------|
| cardiac stress test | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| catheterisation cardiac | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| chest x-ray | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| colonoscopy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| colonoscopy normal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| computerised tomogram coronary artery | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| coronavirus test positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 2 | 1 |
| culture urine positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| echocardiogram | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ejection fraction decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| electrocardiogram qt prolonged | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| endoscopy upper gastrointestinal tract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 9 / 527 (1.71%) | 21 / 1020 (2.06%) | 2 / 389 (0.51%) |
| occurrences (all) | 11 | 28 | 2 |
| glomerular filtration rate decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| haematocrit increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| haemoglobin decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| haemoglobin increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| heart rate decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| heart rate increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| heart rate irregular | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hepatic enzyme increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 10 / 1020 (0.98%) | 3 / 389 (0.77%) |
| occurrences (all) | 6 | 11 | 3 |
| high density lipoprotein increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hormone level abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| influenza a virus test positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| intraocular pressure increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|----------------------|-----------------------|----------------------|
| kl-6 increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| liver function test abnormal alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| liver function test increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 3 / 527 (0.57%) 3 | 4 / 1020 (0.39%) 4 | 1 / 389 (0.26%) 1 |
| lymphocyte count decreased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| lymphocyte morphology abnormal alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| lymphocyte count increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 1 / 389 (0.26%) 1 |
| mammogram alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| neutrophil count increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 2 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| neutrophil count decreased alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| platelet count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| platelet count increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| podiatric examination normal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| prostatic specific antigen increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[36] | 0 / 368 (0.00%) | 1 / 711 (0.14%) | 0 / 279 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| protein urine | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| red blood cell count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| renal function test abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sars-cov-2 test positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 3 / 1020 (0.29%) | 5 / 389 (1.29%) |
| occurrences (all) | 3 | 3 | 5 |

| | | | |
|--|-----------------|------------------|-----------------|
| serum ferritin decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| smear cervix | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[37] | 0 / 159 (0.00%) | 1 / 309 (0.32%) | 0 / 110 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| spermatozoa progressive motility abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[38] | 0 / 368 (0.00%) | 0 / 711 (0.00%) | 1 / 279 (0.36%) |
| occurrences (all) | 0 | 0 | 1 |
| transaminases increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| ultrasound kidney | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ultrasound scan | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| urine leukocyte esterase | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urine output decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vitamin d decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| weight decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 3 / 389 (0.77%) |
| occurrences (all) | 3 | 2 | 3 |
| weight increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 11 / 1020 (1.08%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 11 | 1 |
| white blood cell count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| white blood cell count increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| abdominal injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| accidental overdose | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| animal bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 1 | 2 |
| animal scratch | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| arthropod bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 6 / 1020 (0.59%) | 3 / 389 (0.77%) |
| occurrences (all) | 4 | 8 | 3 |
| arthropod sting | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 1 | 2 |
| avulsion fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 1 | 1 |
| back injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| bone contusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| burns second degree | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|-----------------|------------------|-----------------|
| cartilage injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| chest injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| chillblains | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| clavicle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| concussion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 0 | 1 |
| contusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 7 / 1020 (0.69%) | 5 / 389 (1.29%) |
| occurrences (all) | 4 | 7 | 6 |
| corneal abrasion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| epicondylitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| eye injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| fall | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 10 / 1020 (0.98%) | 1 / 389 (0.26%) |
| occurrences (all) | 3 | 11 | 1 |
| fibula fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| foot fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 3 | 4 | 1 |
| foreign body in eye | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| forearm fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| foreign body in throat | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 3 | 1 |
| heat stroke | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| | | | |
|--|----------------------|-------------------------|----------------------|
| humerus fracture alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 1 / 389 (0.26%) 2 |
| injury alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 2 / 1020 (0.20%) 2 | 0 / 389 (0.00%) 0 |
| joint dislocation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| joint injury alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 3 / 1020 (0.29%) 3 | 1 / 389 (0.26%) 1 |
| ligament rupture alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 1 / 389 (0.26%) 1 |
| limb injury alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 8 / 1020 (0.78%) 8 | 5 / 389 (1.29%) 5 |
| ligament sprain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 6 / 527 (1.14%) 6 | 15 / 1020 (1.47%) 15 | 3 / 389 (0.77%) 3 |
| lower limb fracture alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| lumbar vertebral fracture alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| meniscus injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 2 | 2 |
| muscle injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| muscle rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 1 | 2 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 4 / 1020 (0.39%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 4 | 2 |
| post procedural haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| post vaccination syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| post-traumatic neck syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| procedural nausea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|-----------------|------------------|-----------------|
| procedural pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 9 / 1020 (0.88%) | 2 / 389 (0.51%) |
| occurrences (all) | 7 | 9 | 2 |
| radius fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| retinal injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| scar | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| skin abrasion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 3 | 1 |
| skin laceration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 8 / 527 (1.52%) | 5 / 1020 (0.49%) | 4 / 389 (1.03%) |
| occurrences (all) | 8 | 5 | 5 |
| soft tissue injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| spinal column injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| synovial rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tendon injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| tendon rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 4 | 1 |
| thermal burn | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tooth fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 5 / 1020 (0.49%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 5 | 1 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| vaccination complication | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 13 / 1020 (1.27%) | 4 / 389 (1.03%) |
| occurrences (all) | 3 | 13 | 5 |

| | | | |
|---|----------------------|-----------------------|----------------------|
| vascular pseudoaneurysm alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| wound complication alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| wound alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 4 / 1020 (0.39%) 4 | 0 / 389 (0.00%) 0 |
| wrist fracture alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| Congenital, familial and genetic disorders atrial septal defect alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| block vertebra alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| dermoid cyst alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 1 / 389 (0.26%) 2 |
| hydrocele alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[39] occurrences (all) | 0 / 368 (0.00%) 0 | 1 / 711 (0.14%) 1 | 0 / 279 (0.00%) 0 |
| Cardiac disorders | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| angina pectoris | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| aortic valve incompetence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| aortic valve sclerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| arrhythmia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 3 / 1020 (0.29%) | 2 / 389 (0.51%) |
| occurrences (all) | 5 | 3 | 2 |
| atrioventricular block first degree | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| bradycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| bundle branch block left | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cardiac failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| cardiac failure congestive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| cardiomegaly | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cardiomyopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| cardiovascular disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| coronary artery stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| coronary artery thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| coronary ostial stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| extrasystoles | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| left atrial enlargement | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| left ventricular failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| left ventricular hypertrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| mitral valve incompetence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| myocardial ischaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| palpitations | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| right atrial enlargement | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| right ventricular hypertrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| sinus bradycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| sinus tachycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tachycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 3 | 2 |
| tricuspid valve incompetence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ventricular extrasystoles | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| amnesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| anosmia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| aphasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| arachnoid cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ataxia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| bell's palsy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| burning sensation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| carotid arteriosclerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| carpal tunnel syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 6 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cervical radiculopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cervicobrachial syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| cognitive disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| complex regional pain syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cubital tunnel syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| diabetic neuropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| dizziness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 9 / 1020 (0.88%) | 0 / 389 (0.00%) |
| occurrences (all) | 4 | 9 | 0 |
| facial paralysis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|------------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| generalised tonic-clonic seizure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| headache | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 18 / 527 (3.42%) | 55 / 1020 (5.39%) | 21 / 389 (5.40%) |
| occurrences (all) | 21 | 93 | 32 |
| hemianopia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hyperaesthesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hypoesthesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| lethargy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| loss of consciousness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|---|-----------------|------------------|-----------------|
| lumbar radiculopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| memory impairment | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| migraine | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 6 / 1020 (0.59%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 6 | 1 |
| myelopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nerve compression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| neuralgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 3 | 1 |
| neuropathy peripheral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| paraesthesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |
| peripheral nerve lesion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| peroneal nerve palsy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pineal gland cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| post herpetic neuralgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| psychomotor hyperactivity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| sciatica | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 9 / 1020 (0.88%) | 3 / 389 (0.77%) |
| occurrences (all) | 2 | 11 | 3 |
| seizure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| somnolence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| syncope | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|---|----------------------|-------------------------|----------------------|
| transient aphasia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| tremor alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| anaemia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 4 / 527 (0.76%) 4 | 14 / 1020 (1.37%) 16 | 2 / 389 (0.51%) 2 |
| anaemia macrocytic alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| anaemia of chronic disease alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| bone marrow oedema alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| eosinophilia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| febrile neutropenia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| hypercoagulation alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 0 | 1 |
| leukocytosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 2 |
| leukopenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 3 / 389 (0.77%) |
| occurrences (all) | 0 | 2 | 3 |
| lymphadenitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| lymphadenopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 2 |
| lymphopenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 2 |
| macrocytosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| neutropenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 3 / 389 (0.77%) |
| occurrences (all) | 0 | 1 | 3 |

| | | | |
|---|----------------------|-----------------------|----------------------|
| neutrophilia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| pancytopenia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| splenomegaly alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| thrombocytopenia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 5 / 1020 (0.49%) 5 | 0 / 389 (0.00%) 0 |
| thrombocytosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| Ear and labyrinth disorders cerumen impaction alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| deafness alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 1 / 389 (0.26%) 1 |
| deafness neurosensory alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| deafness unilateral alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| ear discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ear inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ear pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 2 | 2 |
| eustachian tube dysfunction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| eustachian tube obstruction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| external ear inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hypoacusis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 2 |
| inner ear inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|----------------------|-----------------------|----------------------|
| middle ear effusion alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| tinnitus alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 2 / 527 (0.38%) 3 | 4 / 1020 (0.39%) 4 | 0 / 389 (0.00%) 0 |
| tympanic membrane perforation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| vertigo alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 3 / 527 (0.57%) 3 | 6 / 1020 (0.59%) 7 | 3 / 389 (0.77%) 3 |
| vertigo positional alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 2 / 1020 (0.20%) 2 | 0 / 389 (0.00%) 0 |
| Eye disorders arteriosclerotic retinopathy alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| blepharitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| blepharospasm alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| cataract alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 4 | 2 |
| chalazion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| chorioretinopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| conjunctival haemorrhage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| conjunctival hyperaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| conjunctivitis allergic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 2 | 2 |
| diabetic retinopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| dry eye | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| eye allergy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| eye disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| eye irritation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| eye pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| eyelid thickening | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| glaucoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| iridocyclitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lacrimation increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| macular degeneration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ocular hyperaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ocular surface disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| open angle glaucoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| optic disc drusen | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| optic neuropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 2 |
| trichiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ulcerative keratitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vision blurred | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| vitreous detachment | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|---|----------------------|-------------------------|-----------------------|
| vitreous haemorrhage alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| vitreous prolapse alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 2 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| abdominal discomfort alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 3 / 1020 (0.29%) 3 | 1 / 389 (0.26%) 1 |
| abdominal distension alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 2 / 389 (0.51%) 2 |
| abdominal hernia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| abdominal pain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 2 | 13 / 1020 (1.27%) 15 | 5 / 389 (1.29%) 17 |
| abdominal pain lower alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| abdominal pain upper alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 3 / 527 (0.57%) 4 | 9 / 1020 (0.88%) 10 | 6 / 389 (1.54%) 6 |
| angular cheilitis alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| anorectal discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| cheilitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| chronic gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| colitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 1 | 1 |
| constipation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 9 / 1020 (0.88%) | 4 / 389 (1.03%) |
| occurrences (all) | 2 | 9 | 5 |
| dental caries | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 12 / 1020 (1.18%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 13 | 2 |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 15 / 527 (2.85%) | 20 / 1020 (1.96%) | 9 / 389 (2.31%) |
| occurrences (all) | 15 | 21 | 33 |
| dry mouth | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| duodenitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| dyspepsia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 6 / 1020 (0.59%) | 5 / 389 (1.29%) |
| occurrences (all) | 3 | 9 | 16 |
| dysphagia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| enteritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| enterocolitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| epiploic appendagitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| flatulence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| food poisoning | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 3 | 1 |
| gastric polyps | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| gastric ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 8 / 1020 (0.78%) | 2 / 389 (0.51%) |
| occurrences (all) | 4 | 10 | 2 |
| gastritis erosive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| gastrointestinal disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| gastrointestinal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 8 / 1020 (0.78%) | 3 / 389 (0.77%) |
| occurrences (all) | 5 | 9 | 3 |
| gingival pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| glossitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| haematochezia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| haemorrhagic erosive gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 3 / 389 (0.77%) |
| occurrences (all) | 1 | 3 | 3 |
| hiatus hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hyperaesthesia teeth | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ileus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 3 / 389 (0.77%) |
| occurrences (all) | 2 | 1 | 3 |
| intra-abdominal haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| irritable bowel syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 1 | 1 |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| lip swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| lip erosion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lumbar hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| melaena | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| mouth ulceration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 12 / 1020 (1.18%) | 1 / 389 (0.26%) |
| occurrences (all) | 4 | 19 | 1 |
| noninfective sialoadenitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| odynophagia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 2 | 1 |
| oesophageal obstruction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| oesophagitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| oral hyperkeratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| oral lichen planus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| oral papule | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pancreatic disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| periodontal disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 6 / 1020 (0.59%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 6 | 1 |
| proctitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| rectal polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| stomatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| terminal ileitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| tooth impacted | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| toothache | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 16 / 1020 (1.57%) | 9 / 389 (2.31%) |
| occurrences (all) | 5 | 19 | 9 |
| umbilical hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vomiting | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 5 / 1020 (0.49%) | 1 / 389 (0.26%) |
| occurrences (all) | 5 | 5 | 1 |

| | | | |
|---|-----------------|------------------|-----------------|
| Hepatobiliary disorders | | | |
| biliary colic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| cholangitis acute | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cholecystitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| cholelithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 8 / 1020 (0.78%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 8 | 2 |
| fatty liver alcoholic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| gallbladder polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 3 / 389 (0.77%) |
| occurrences (all) | 0 | 0 | 3 |
| hepatic cirrhosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hepatic cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| hepatic function abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 3 / 527 (0.57%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 4 | 0 |
| hepatic steatosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 12 / 1020 (1.18%) | 2 / 389 (0.51%) |
| occurrences (all) | 5 | 12 | 2 |
| hepatitis alcoholic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hepatomegaly | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| liver disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| non-alcoholic steatohepatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| nonalcoholic fatty liver disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| primary biliary cholangitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| acanthosis nigricans | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| acne | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 6 / 1020 (0.59%) | 4 / 389 (1.03%) |
| occurrences (all) | 4 | 6 | 4 |
| acne varioliformis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| actinic keratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 5 / 1020 (0.49%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 5 | 2 |
| alopecia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| alopecia areata | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| angioedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 2 |
| asteatosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| dermal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 3 | 1 |
| dermatitis contact | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 10 / 1020 (0.98%) | 5 / 389 (1.29%) |
| occurrences (all) | 4 | 12 | 8 |
| dermatitis papillaris capillitii | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| diabetic foot | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| drug eruption | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 0 | 2 |
| dry skin | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 3 | 3 |
| dyshidrotic eczema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 4 | 1 |
| eczema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 10 / 1020 (0.98%) | 3 / 389 (0.77%) |
| occurrences (all) | 4 | 10 | 3 |
| eczema asteatotic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 1 | 2 |
| eczema nummular | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| hand dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hyperhidrosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| hyperkeratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| ingrowing nail | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 0 | 1 |
| intertrigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 3 | 5 | 1 |
| itching scar | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| lichen planus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lichen sclerosus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lichenification | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lichenoid keratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| mechanical urticaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| milia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| miliaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 3 |
| nail discolouration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| nail dystrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| neurodermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| night sweats | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| onycholysis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| palmar erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 0 | 2 |
| papule | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| photosensitivity reaction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 2 |
| post inflammatory pigmentation change | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| prurigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|---|------------------|-------------------|-----------------|
| pruritus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 12 / 527 (2.28%) | 17 / 1020 (1.67%) | 6 / 389 (1.54%) |
| occurrences (all) | 12 | 20 | 7 |
| psoriasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| rash | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 5 / 1020 (0.49%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 5 | 2 |
| rosacea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| seborrhoeic dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| skin burning sensation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| skin erosion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| skin exfoliation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| skin fissures | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 1 | 2 |
| skin lesion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| skin tightness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| skin plaque | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| skin ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| stasis dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| urticaria physical | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 12 / 1020 (1.18%) | 1 / 389 (0.26%) |
| occurrences (all) | 5 | 12 | 1 |
| vitiligo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| chronic kidney disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| cystitis noninfective | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| dysuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| glycosuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| haematuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 3 | 1 |
| haemorrhage urinary tract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hydronephrosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ketonuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| kidney congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| leukocyturia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nephritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 5 / 1020 (0.49%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 8 | 0 |
| nocturia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| pollakiuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| proteinuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| renal colic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |

| | | | |
|---|----------------------|-----------------------|----------------------|
| renal cyst alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 2 / 527 (0.38%) 2 | 3 / 1020 (0.29%) 3 | 3 / 389 (0.77%) 3 |
| renal failure alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| renal impairment alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| ureterolithiasis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 2 / 1020 (0.20%) 2 | 0 / 389 (0.00%) 0 |
| Endocrine disorders | | | |
| acromegaly alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| autoimmune thyroiditis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| goitre alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| hyperparathyroidism alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| hyperprolactinaemia alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|------------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hyperthyroidism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 1 | 2 |
| hypogonadism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| hypothyroidism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 6 / 1020 (0.59%) | 1 / 389 (0.26%) |
| occurrences (all) | 4 | 6 | 1 |
| thyroid mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 30 / 527 (5.69%) | 87 / 1020 (8.53%) | 19 / 389 (4.88%) |
| occurrences (all) | 36 | 95 | 23 |
| arthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 10 / 1020 (0.98%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 10 | 2 |
| arthropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| axillary mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|------------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| back pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 25 / 527 (4.74%) | 48 / 1020 (4.71%) | 20 / 389 (5.14%) |
| occurrences (all) | 27 | 61 | 22 |
| bursitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 6 / 1020 (0.59%) | 0 / 389 (0.00%) |
| occurrences (all) | 4 | 6 | 0 |
| cervical spinal stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| chondrocalcinosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| chondropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| costochondritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| dactylitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 5 | 1 | 2 |
| enthesopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| exostosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| fibromyalgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| flank pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 0 | 1 |
| groin pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| haemarthrosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| intervertebral disc degeneration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| intervertebral disc disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 7 / 1020 (0.69%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 7 | 2 |
| intervertebral disc space narrowing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| joint effusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| joint stiffness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| ligament disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ligament pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| lumbar spinal stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| muscle contracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| muscle spasms | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 9 / 1020 (0.88%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 10 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| muscle tightness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| musculoskeletal chest pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 4 | 1 |
| myalgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 12 / 1020 (1.18%) | 3 / 389 (0.77%) |
| occurrences (all) | 7 | 16 | 3 |
| musculoskeletal stiffness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| myositis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| neck pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 9 / 1020 (0.88%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 9 | 3 |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 8 / 1020 (0.78%) | 4 / 389 (1.03%) |
| occurrences (all) | 7 | 8 | 4 |
| osteopenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|------------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| osteoporosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 22 / 1020 (2.16%) | 7 / 389 (1.80%) |
| occurrences (all) | 7 | 28 | 8 |
| pain in jaw | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| patellofemoral pain syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| periarthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| plantar fasciitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| psoriatic arthropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 9 / 527 (1.71%) | 12 / 1020 (1.18%) | 10 / 389 (2.57%) |
| occurrences (all) | 9 | 12 | 12 |
| rheumatic disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 4 | 2 |
| sacroiliitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| scoliosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| spinal osteoarthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 7 / 1020 (0.69%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 7 | 2 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 7 / 1020 (0.69%) | 1 / 389 (0.26%) |
| occurrences (all) | 6 | 11 | 1 |
| spinal retrolisthesis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| spondylolisthesis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| synovial cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| synovitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 5 | 3 | 1 |
| tendon disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| tendonitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 10 / 1020 (0.98%) | 4 / 389 (1.03%) |
| occurrences (all) | 1 | 10 | 4 |
| tenosynovitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| tenosynovitis stenosans | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| trigger finger | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Infections and infestations | | | |
| abdominal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| abscess jaw | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| abscess limb | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| acarodermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| acute sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 6 | 0 |
| adenoviral conjunctivitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| appendicitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| asymptomatic covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|------------------|-------------------|------------------|
| bacterial vaginosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[40] | 0 / 159 (0.00%) | 0 / 309 (0.00%) | 1 / 110 (0.91%) |
| occurrences (all) | 0 | 0 | 1 |
| body tinea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 1 | 1 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 10 / 527 (1.90%) | 24 / 1020 (2.35%) | 4 / 389 (1.03%) |
| occurrences (all) | 11 | 25 | 4 |
| bronchitis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 33 / 527 (6.26%) | 66 / 1020 (6.47%) | 26 / 389 (6.68%) |
| occurrences (all) | 33 | 67 | 28 |
| covid-19 pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| candida infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| cellulitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 6 / 1020 (0.59%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 6 | 2 |
| chronic sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| conjunctivitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 8 / 1020 (0.78%) | 2 / 389 (0.51%) |
| occurrences (all) | 4 | 8 | 2 |
| conjunctivitis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| conjunctivitis viral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| coronavirus infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| coronavirus pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cystitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 7 / 1020 (0.69%) | 2 / 389 (0.51%) |
| occurrences (all) | 4 | 8 | 2 |
| cystitis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| dermatophytosis of nail | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|------------------|-----------------|
| diverticulitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 3 / 389 (0.77%) |
| occurrences (all) | 0 | 2 | 4 |
| ear infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| endocarditis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| enterococcal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| epididymitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[41] | 0 / 368 (0.00%) | 3 / 711 (0.42%) | 0 / 279 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 2 | 1 |
| erythema migrans | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| erythrasma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| folliculitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 7 / 527 (1.33%) | 6 / 1020 (0.59%) | 3 / 389 (0.77%) |
| occurrences (all) | 7 | 6 | 3 |
| fungus infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| fungus skin infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| furuncle | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 6 / 1020 (0.59%) | 4 / 389 (1.03%) |
| occurrences (all) | 1 | 8 | 6 |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 15 / 1020 (1.47%) | 3 / 389 (0.77%) |
| occurrences (all) | 6 | 17 | 3 |
| gastroenteritis norovirus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 0 | 1 |
| gastroenteritis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| gastroenteritis viral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 6 / 1020 (0.59%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 6 | 1 |
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 5 / 1020 (0.49%) | 0 / 389 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |

| | | | |
|---|----------------------|-----------------------|----------------------|
| gastrointestinal viral infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| genital candidiasis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| genital herpes alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 3 |
| genital herpes simplex alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| genital infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 0 / 389 (0.00%) 0 |
| gingivitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 3 / 527 (0.57%) 3 | 5 / 1020 (0.49%) 5 | 1 / 389 (0.26%) 1 |
| helicobacter infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 2 / 527 (0.38%) 2 | 2 / 1020 (0.20%) 2 | 0 / 389 (0.00%) 0 |
| hepatitis a alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 1 / 1020 (0.10%) 1 | 0 / 389 (0.00%) 0 |
| herpangina alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| herpes simplex | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| herpes zoster | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 6 / 527 (1.14%) | 7 / 1020 (0.69%) | 4 / 389 (1.03%) |
| occurrences (all) | 6 | 8 | 4 |
| herpes zoster infection neurological | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| histoplasmosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| hordeolum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 3 | 1 |
| impetigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 2 | 1 |
| infected cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| influenza | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 18 / 1020 (1.76%) | 2 / 389 (0.51%) |
| occurrences (all) | 4 | 18 | 2 |

| | | | |
|---|-----------------|------------------|-----------------|
| injection site infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| intervertebral discitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| laryngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 2 | 2 |
| latent tuberculosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 4 / 1020 (0.39%) | 4 / 389 (1.03%) |
| occurrences (all) | 4 | 4 | 4 |
| localised infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 1 | 2 |
| lyme disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| lymphogranuloma venereum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| molluscum contagiosum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-------------------|------------------------|-------------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| mucocutaneous candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| mycobacterial infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| myringitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 55 / 527 (10.44%) | 157 / 1020 (15.39%) | 43 / 389 (11.05%) |
| occurrences (all) | 69 | 226 | 57 |
| onychomycosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 1 | 2 |
| ophthalmic herpes simplex | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| oral candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| oral fungal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| oral herpes | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 7 / 527 (1.33%) | 11 / 1020 (1.08%) | 2 / 389 (0.51%) |
| occurrences (all) | 9 | 12 | 2 |
| oral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| oropharyngeal candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| otitis media | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 5 / 1020 (0.49%) | 2 / 389 (0.51%) |
| occurrences (all) | 1 | 5 | 2 |
| otitis externa | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 4 | 0 |
| papilloma viral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| paronychia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| parotitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pericoronitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|------------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| perineal abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| periodontitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 4 / 1020 (0.39%) | 2 / 389 (0.51%) |
| occurrences (all) | 0 | 4 | 2 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 9 / 527 (1.71%) | 17 / 1020 (1.67%) | 10 / 389 (2.57%) |
| occurrences (all) | 11 | 19 | 10 |
| pharyngitis streptococcal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 2 | 4 | 1 |
| pharyngotonsillitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 5 / 1020 (0.49%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| pilonidal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 3 | 1 |
| post procedural infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|----------------------|-------------------------|----------------------|
| postoperative wound infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 527 (0.19%) 1 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| pulpitis dental alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 3 / 527 (0.57%) 3 | 3 / 1020 (0.29%) 5 | 2 / 389 (0.51%) 2 |
| rash pustular alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| respiratory tract infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 4 / 527 (0.76%) 4 | 8 / 1020 (0.78%) 9 | 4 / 389 (1.03%) 4 |
| respiratory tract infection viral alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| rhinitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 5 / 527 (0.95%) 5 | 11 / 1020 (1.08%) 12 | 3 / 389 (0.77%) 3 |
| rhinovirus infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 2 / 389 (0.51%) 2 |
| root canal infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| salmonellosis alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 1 | 1 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 7 / 527 (1.33%) | 21 / 1020 (2.06%) | 7 / 389 (1.80%) |
| occurrences (all) | 8 | 23 | 8 |
| skin candida | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| skin infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 2 | 1 |
| soft tissue infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| subcutaneous abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| superinfection mycobacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| superinfection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| suspected covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| testicular abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[42] | 1 / 368 (0.27%) | 0 / 711 (0.00%) | 0 / 279 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tinea cruris | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| tinea infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 12 / 1020 (1.18%) | 4 / 389 (1.03%) |
| occurrences (all) | 8 | 13 | 4 |
| tinea versicolour | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 7 / 1020 (0.69%) | 1 / 389 (0.26%) |
| occurrences (all) | 6 | 9 | 1 |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 10 / 1020 (0.98%) | 5 / 389 (1.29%) |
| occurrences (all) | 5 | 10 | 5 |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 4 / 1020 (0.39%) | 1 / 389 (0.26%) |
| occurrences (all) | 3 | 4 | 1 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 10 / 1020 (0.98%) | 4 / 389 (1.03%) |
| occurrences (all) | 5 | 11 | 4 |
| trichophytosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|------------------|-------------------|------------------|
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tuberculosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 22 / 527 (4.17%) | 54 / 1020 (5.29%) | 29 / 389 (7.46%) |
| occurrences (all) | 29 | 64 | 42 |
| urethritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 11 / 527 (2.09%) | 30 / 1020 (2.94%) | 9 / 389 (2.31%) |
| occurrences (all) | 14 | 38 | 9 |
| urinary tract infection enterococcal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vaginal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[43] | 1 / 159 (0.63%) | 3 / 309 (0.97%) | 0 / 110 (0.00%) |
| occurrences (all) | 1 | 8 | 0 |
| viral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| viral sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|----------------------|-------------------------|----------------------|
| viral upper respiratory tract infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 2 / 527 (0.38%) 2 | 4 / 1020 (0.39%) 4 | 2 / 389 (0.51%) 2 |
| vulvovaginal candidiasis alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[44] occurrences (all) | 1 / 159 (0.63%) 1 | 2 / 309 (0.65%) 4 | 1 / 110 (0.91%) 1 |
| vulvovaginal mycotic infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[45] occurrences (all) | 3 / 159 (1.89%) 3 | 1 / 309 (0.32%) 1 | 2 / 110 (1.82%) 2 |
| vulvovaginitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[46] occurrences (all) | 0 / 159 (0.00%) 0 | 0 / 309 (0.00%) 0 | 1 / 110 (0.91%) 1 |
| wound infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 2 / 389 (0.51%) 2 |
| Metabolism and nutrition disorders abnormal weight gain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 0 / 1020 (0.00%) 0 | 1 / 389 (0.26%) 1 |
| decreased appetite alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 527 (0.00%) 0 | 4 / 1020 (0.39%) 4 | 1 / 389 (0.26%) 1 |
| diabetes mellitus alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 5 / 527 (0.95%) 5 | 12 / 1020 (1.18%) 13 | 2 / 389 (0.51%) 2 |
| dyslipidaemia alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-------------------|-----------------|
| subjects affected / exposed | 4 / 527 (0.76%) | 5 / 1020 (0.49%) | 3 / 389 (0.77%) |
| occurrences (all) | 4 | 5 | 3 |
| glucose tolerance impaired | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| gout | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 9 / 1020 (0.88%) | 3 / 389 (0.77%) |
| occurrences (all) | 3 | 13 | 4 |
| hypercalcaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hypercholesterolaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 4 / 527 (0.76%) | 12 / 1020 (1.18%) | 3 / 389 (0.77%) |
| occurrences (all) | 4 | 14 | 3 |
| hyperglycaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 527 (0.38%) | 10 / 1020 (0.98%) | 2 / 389 (0.51%) |
| occurrences (all) | 2 | 10 | 2 |
| hyperkalaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 1 / 389 (0.26%) |
| occurrences (all) | 1 | 2 | 1 |
| hyperlipidaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 11 / 1020 (1.08%) | 0 / 389 (0.00%) |
| occurrences (all) | 3 | 11 | 0 |
| hypernatraemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-------------------|-----------------|
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 17 / 1020 (1.67%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 28 | 0 |
| hyperuricaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 5 / 1020 (0.49%) | 1 / 389 (0.26%) |
| occurrences (all) | 5 | 6 | 1 |
| hypokalaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| hypomagnesaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 2 / 1020 (0.20%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| hyponatraemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 3 / 1020 (0.29%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| hypovitaminosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| impaired fasting glucose | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| insulin resistance | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 527 (0.19%) | 0 / 1020 (0.00%) | 0 / 389 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| iron deficiency | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 527 (0.00%) | 0 / 1020 (0.00%) | 1 / 389 (0.26%) |
| occurrences (all) | 0 | 0 | 1 |
| overweight | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 527 (0.95%) | 8 / 1020 (0.78%) | 5 / 389 (1.29%) |
| occurrences (all) | 5 | 8 | 5 |
| underweight | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 1 / 1020 (0.10%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vitamin b12 deficiency | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 527 (0.00%) | 4 / 1020 (0.39%) | 0 / 389 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| vitamin d deficiency | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 3 / 527 (0.57%) | 5 / 1020 (0.49%) | 2 / 389 (0.51%) |
| occurrences (all) | 3 | 5 | 2 |

| Non-serious adverse events | 125 Milligram (mg) Mirikizumab Q8W Follow-up Period | 250 mg Mirikizumab Q8W Excluding Secukinumab Follow-up Period | Secukinumab/250 mg Mirikizumab Q8W Follow-up Period |
|--|---|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 70 / 453 (15.45%) | 120 / 861 (13.94%) | 47 / 333 (14.11%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| acrochordon | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| adenoma benign | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| anogenital warts | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| basal cell carcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| benign breast neoplasm | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| benign hepatobiliary neoplasm | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| benign neoplasm of thyroid gland | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| benign vascular neoplasm | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bowen's disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| colon adenoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| dysplastic naevus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| fibroma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| fibrous histiocytoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| focal nodular hyperplasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| haemangioma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lentigo maligna | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lipoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| malignant ascites | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| melanocytic naevus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| meningioma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| neoplasm malignant | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pituitary tumour benign | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| prostate cancer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[9] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pyogenic granuloma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| seborrhoeic keratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin papilloma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| squamous cell carcinoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| uterine leiomyoma alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[10] occurrences (all) | 0 / 130 (0.00%) 0 | 0 / 259 (0.00%) 0 | 0 / 89 (0.00%) 0 |
| Vascular disorders | | | |
| aortic thrombosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| arteriosclerosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| deep vein thrombosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| essential hypertension alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| flushing alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| haematoma alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| hot flush alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| hypertension alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 3 / 861 (0.35%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| hypertensive crisis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypotension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| jugular vein thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lymphoedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lymphorrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| orthostatic hypotension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| peripheral artery occlusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| peripheral venous disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------------------|---------------------------------|---------------------------------|
| <p>phlebitis superficial</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>post thrombotic syndrome</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>thrombosis</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>varicose vein</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>white coat hypertension</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>Surgical and medical procedures</p> <p>abscess drainage</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>acrochordon excision</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>ankle operation</p> <p>alternative dictionary used: MedDRA 24.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 453 (0.00%)</p> <p>0</p> | <p>0 / 861 (0.00%)</p> <p>0</p> | <p>0 / 333 (0.00%)</p> <p>0</p> |
| <p>appendicectomy</p> <p>alternative dictionary used: MedDRA 24.1</p> | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiac ablation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardioversion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| carpal tunnel decompression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cataract operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| cholecystectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| circumcision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[11] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| corneal transplant | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronary revascularisation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| dental care | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| dental implantation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| endodontic procedure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| endoscopic sleeve gastroplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eyelid cyst removal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| finger amputation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastric bypass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hernia hiatus repair | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hernia repair | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hysterectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[12] | 0 / 130 (0.00%) | 1 / 259 (0.39%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| internal fixation of fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intra-uterine contraceptive device insertion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[13] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intraocular lens implant | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| knee arthroplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| knee operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| laparoscopic surgery | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| large intestinal polypectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| lens extraction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lipolysis procedure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lipoma excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lithotripsy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| open reduction of fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| papilloma excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| percutaneous coronary intervention | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| peripheral nerve neurostimulation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| phlebectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| polypectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pterygium operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rhinoplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus operation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| skin neoplasm excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| splint application | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| suture insertion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| tenoplasty | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tonsillectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| tooth extraction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| tooth restoration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tumour excision | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| uterine dilation and curettage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[14] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vasectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[15] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vitrectomy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wisdom teeth removal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| wound drainage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| adverse drug reaction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| asthenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chest discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chest pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chills | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| effusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| fatigue | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 2 / 333 (0.60%) |
| occurrences (all) | 0 | 0 | 2 |
| granuloma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperthermia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| implant site irritation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza like illness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| injection site discolouration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site bruising | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injection site erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| injection site haematoma alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site induration alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site inflammation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site oedema alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site pain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site rash alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site pruritus alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| injection site swelling alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 1 / 861 (0.12%) 1 | 0 / 333 (0.00%) 0 |
| injection site reaction alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| lithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| malaise | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| mucosal inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nodule | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| non-cardiac chest pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oedema peripheral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| peripheral swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| puncture site pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pyrexia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 453 (1.10%) | 2 / 861 (0.23%) | 1 / 333 (0.30%) |
| occurrences (all) | 5 | 2 | 1 |
| swelling face | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| temperature regulation disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tenderness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vaccination site joint pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vaccination site oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vaccination site swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| vaccination site pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| xerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| allergy to animal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| allergy to arthropod bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| allergy to arthropod sting | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| anaphylactic reaction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| drug hypersensitivity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| food allergy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

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|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypersensitivity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| seasonal allergy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| adenomyosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[16] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| balanoposthitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[17] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| benign prostatic hyperplasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[18] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| breast calcifications | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| breast cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| breast disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| breast mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| breast pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cervical cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[19] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dysmenorrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[20] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| endometrial thickening | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[21] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| endometriosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[22] | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| erectile dysfunction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[23] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| genital erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| genital lesion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| heavy menstrual bleeding | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[24] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intermenstrual bleeding | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[25] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menopausal symptoms | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[26] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| menstruation irregular | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[27] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ovarian cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[28] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| perineal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| perineal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| polycystic ovaries | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed ^[29] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| premenstrual pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[30] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| prostatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[31] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pruritus genital | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| uterine cervical metaplasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[32] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vulval eczema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[33] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vulvovaginal inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[34] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vulvovaginal pruritus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[35] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| allergic cough | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| allergic pharyngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| asthma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| atelectasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bronchitis chronic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| catarrh | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| chronic obstructive pulmonary disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cough | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| cough variant asthma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| dysphonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dyspnoea exertional | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dyspnoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| epistaxis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hiccups | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hyperventilation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| laryngeal disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lower respiratory tract congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| nasal congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal septum deviation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal polyps | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal turbinate abnormality | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal turbinate hypertrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasal ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| oropharyngeal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 2 / 861 (0.23%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 2 | 1 |
| paranasal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| paranasal sinus discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pleural effusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| productive cough | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pulmonary hypertension | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pulmonary mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pulmonary oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rhinitis allergic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| rhinorrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| sinonasal obstruction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sleep apnoea syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sneezing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| throat irritation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| upper respiratory tract inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vocal cord leukoplakia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vocal cord polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| wheezing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Psychiatric disorders | | | |
| adjustment disorder with depressed mood | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| affective disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| alcohol abuse | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| anxiety | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| attention deficit hyperactivity disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| confusional state | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| depression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| depressed mood | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| distractibility | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dysphoria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| initial insomnia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| insomnia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| major depression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mental fatigue | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mental status changes | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mood swings | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| panic attack | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sleep disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| stress | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| suicidal ideation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| suicidal behaviour | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| suicide attempt | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| alanine aminotransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| arthroscopy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aspartate aminotransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aspiration joint | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| basophil count increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bilirubin conjugated increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| biopsy lymph gland | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| biopsy skin | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood alkaline phosphatase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| blood bilirubin increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood cholesterol increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| blood creatine phosphokinase increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 0 / 861 (0.00%) 0 | 2 / 333 (0.60%) 2 |
| blood creatinine increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blood gastrin increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blood glucose increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 2 / 861 (0.23%) 2 | 0 / 333 (0.00%) 0 |
| blood iron decreased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blood parathyroid hormone increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blood potassium increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blood pressure abnormal alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blood pressure increased alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood testosterone decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood thyroid stimulating hormone increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood triglycerides increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| blood urea increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| blood uric acid increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| body height decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| body temperature increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bone scan | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| cardiac murmur | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiac stress test | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| catheterisation cardiac | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chest x-ray | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| colonoscopy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| colonoscopy normal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| computerised tomogram coronary artery | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronavirus test positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| culture urine positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| echocardiogram | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ejection fraction decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| electrocardiogram qt prolonged | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| endoscopy upper gastrointestinal tract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| gamma-glutamyltransferase increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| glomerular filtration rate decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haematocrit increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haemoglobin decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haemoglobin increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| heart rate decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| heart rate increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| heart rate irregular | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatic enzyme increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| high density lipoprotein increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hormone level abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| influenza a virus test positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| intraocular pressure increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| kl-6 increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| liver function test abnormal alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| liver function test increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 1 / 861 (0.12%) 1 | 0 / 333 (0.00%) 0 |
| lymphocyte count decreased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| lymphocyte morphology abnormal alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| lymphocyte count increased alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| mammogram alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| neutrophil count increased alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| neutrophil count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| platelet count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| platelet count increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| podiatric examination normal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| prostatic specific antigen increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[36] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| protein urine | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| red blood cell count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| renal function test abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|--|-----------------|-----------------|-----------------|
| sars-cov-2 test positive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| serum ferritin decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| smear cervix | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[37] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spermatozoa progressive motility abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[38] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| transaminases increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ultrasound kidney | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ultrasound scan | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urine leukocyte esterase | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| urine output decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vitamin d decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| weight increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| white blood cell count decreased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| white blood cell count increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| abdominal injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| accidental overdose | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| animal bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| animal scratch | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ankle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arthropod bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| arthropod sting | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| avulsion fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bite | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bone contusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| burns second degree | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cartilage injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chest injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chillblains | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| clavicle fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| concussion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| contusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 1 / 333 (0.30%) |
| occurrences (all) | 1 | 1 | 1 |
| corneal abrasion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| epicondylitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eye injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| fall | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| fibula fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| foot fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| foreign body in eye | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| forearm fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| foreign body in throat | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hand fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|-----------------|-----------------|-----------------|
| heat stroke | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| humerus fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint dislocation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ligament rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| limb injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| ligament sprain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 1 | 0 | 2 |
| lower limb fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lumbar vertebral fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| meniscus injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle strain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| post procedural haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| post vaccination syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| post-traumatic neck syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| procedural nausea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| procedural pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 453 (0.44%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| radius fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| retinal injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rib fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| road traffic accident | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| scar | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin abrasion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin laceration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| soft tissue injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spinal column injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| synovial rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tendon injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tendon rupture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| thermal burn | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper limb fracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| vaccination complication alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 1 / 861 (0.12%) 1 | 2 / 333 (0.60%) 3 |
| vascular pseudoaneurysm alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| wound complication alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| wound alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| wrist fracture alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Congenital, familial and genetic disorders atrial septal defect alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| block vertebra alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| dermoid cyst alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| hydrocele alternative dictionary used: | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| MedDRA 24.1 | | | |
| subjects affected / exposed ^[39] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| angina pectoris | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| angina unstable | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aortic valve incompetence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aortic valve sclerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arrhythmia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| atrial fibrillation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| atrioventricular block first degree | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bradycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bundle branch block left | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiac failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiac failure congestive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiomegaly | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiomyopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cardiovascular disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronary artery disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronary artery stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|-----------------|-----------------|-----------------|
| coronary artery thrombosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronary ostial stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| extrasystoles | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| left atrial enlargement | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| left ventricular failure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| left ventricular hypertrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mitral valve incompetence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| myocardial ischaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| palpitations | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pericarditis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| right atrial enlargement | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| right ventricular hypertrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus bradycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinus tachycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tachycardia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tricuspid valve incompetence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ventricular extrasystoles | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Nervous system disorders | | | |
| amnesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| anosmia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| aphasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arachnoid cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ataxia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bell's palsy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| burning sensation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| carotid arteriosclerosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| carpal tunnel syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cerebrovascular accident | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cervical radiculopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cervicobrachial syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cognitive disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| complex regional pain syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cubital tunnel syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| diabetic neuropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dizziness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| facial paralysis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| generalised tonic-clonic seizure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| headache | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 453 (0.44%) | 7 / 861 (0.81%) | 2 / 333 (0.60%) |
| occurrences (all) | 2 | 7 | 2 |
| hemianopia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hemiparesis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperaesthesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypoesthesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lethargy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| loss of consciousness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lumbar radiculopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| memory impairment | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| migraine | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| myelopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nerve compression | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| neuralgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| neuropathy peripheral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| paraesthesia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| peripheral nerve lesion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| peroneal nerve palsy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pineal gland cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| post herpetic neuralgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| psychomotor hyperactivity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sciatica | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 1 | 0 | 1 |
| seizure | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| somnolence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| syncope | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| transient aphasia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tremor | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| anaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| anaemia macrocytic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| anaemia of chronic disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bone marrow oedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eosinophilia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| febrile neutropenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypercoagulation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| iron deficiency anaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| leukocytosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| leukopenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 1 | 1 |
| lymphadenitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lymphadenopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lymphopenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| macrocytosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| neutropenia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 1 / 333 (0.30%) 1 |
| neutrophilia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| pancytopenia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| splenomegaly alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| thrombocytopenia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| thrombocytosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Ear and labyrinth disorders cerumen impaction alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| deafness alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| deafness neurosensory alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| deafness unilateral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ear discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ear inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ear pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eustachian tube dysfunction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eustachian tube obstruction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| external ear inflammation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypoacusis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| inner ear inflammation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| middle ear effusion alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| tinnitus alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| tympanic membrane perforation alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| vertigo alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| vertigo positional alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Eye disorders arteriosclerotic retinopathy alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blepharitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| blepharospasm alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| cataract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chalazion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chorioretinopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctival haemorrhage | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctival hyperaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctivitis allergic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| diabetic retinopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dry eye | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| eye allergy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eye disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eye irritation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eye pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eyelid thickening | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| glaucoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| iridocyclitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lacrimation increased | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| macular degeneration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ocular hyperaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ocular surface disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| open angle glaucoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| optic disc drusen | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| optic neuropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| trichiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ulcerative keratitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vision blurred | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| vitreous detachment alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| vitreous haemorrhage alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| vitreous prolapse alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Gastrointestinal disorders abdominal discomfort alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| abdominal distension alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| abdominal hernia alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| abdominal pain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| abdominal pain lower alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| abdominal pain upper alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| angular cheilitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| anorectal discomfort | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cheilitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chronic gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| colitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| constipation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| dental caries | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 1 | 1 |
| diarrhoea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 3 / 861 (0.35%) | 2 / 333 (0.60%) |
| occurrences (all) | 1 | 3 | 2 |

| | | | |
|---|-----------------|-----------------|-----------------|
| dry mouth | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| duodenitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dyspepsia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dysphagia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| enteritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| enterocolitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| epiploic appendagitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| flatulence | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| food poisoning | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastric polyps | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastric ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| gastritis erosive | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| gastrointestinal disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrointestinal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| gastrooesophageal reflux disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gingival pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| glossitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haematochezia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haemorrhagic erosive gastritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haemorrhoids | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hiatus hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperaesthesia teeth | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ileus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| inguinal hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intra-abdominal haematoma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| irritable bowel syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| large intestine polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| lip swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lip erosion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lumbar hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| melaena | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mouth ulceration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nausea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 2 / 453 (0.44%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| noninfective sialoadenitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| odynophagia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 1 | 0 | 1 |
| oesophageal obstruction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oesophagitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral hyperkeratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral lichen planus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral papule | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pancreatic disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| periodontal disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| proctitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rectal polyp | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| stomatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| terminal ileitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tooth disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth impacted | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| toothache | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| umbilical hernia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| vomiting alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Hepatobiliary disorders | | | |
| biliary colic alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 1 / 861 (0.12%) 1 | 0 / 333 (0.00%) 0 |
| cholangitis acute alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| cholecystitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| cholelithiasis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| fatty liver alcoholic alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| gallbladder polyp alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| hepatic cirrhosis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| hepatic cyst alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatic function abnormal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatic steatosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis alcoholic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatomegaly | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| liver disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| non-alcoholic steatohepatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nonalcoholic fatty liver disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| primary biliary cholangitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Skin and subcutaneous tissue disorders | | | |
| acanthosis nigricans | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| acne | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| acne varioliformis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| actinic keratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| alopecia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| alopecia areata | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| angioedema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| asteatosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dermal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| dermatitis contact | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dermatitis papillaris capillitii | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| diabetic foot | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| drug eruption | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dry skin | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dyshidrotic eczema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| eczema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| eczema asteatotic | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| eczema nummular | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hand dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperhidrosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperkeratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ingrowing nail | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intertrigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| itching scar | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| lichen planus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lichen sclerosus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lichenification | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lichenoid keratosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mechanical urticaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| milia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| miliaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nail discolouration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| nail dystrophy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| neurodermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| night sweats | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| onycholysis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| palmar erythema | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| papule | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| photosensitivity reaction | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| post inflammatory pigmentation change | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| prurigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pruritus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| psoriasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rash | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rosacea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| seborrhoeic dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| skin burning sensation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin erosion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin exfoliation | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| skin fissures | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin lesion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin tightness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin plaque | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| skin ulcer | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| stasis dermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urticaria physical | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| urticaria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vitiligo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| acute kidney injury | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chronic kidney disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cystitis noninfective | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dysuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| glycosuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| haematuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| haemorrhage urinary tract | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hydronephrosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ketonuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| kidney congestion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| leukocyturia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nephritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nephrolithiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nocturia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pollakiuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| proteinuria | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| renal colic alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| renal cyst alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| renal failure alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| renal impairment alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 1 / 333 (0.30%) 1 |
| ureterolithiasis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Endocrine disorders acromegaly alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| autoimmune thyroiditis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| goitre alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 1 / 861 (0.12%) 1 | 0 / 333 (0.00%) 0 |
| hyperparathyroidism alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperprolactinaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperthyroidism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypogonadism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypothyroidism | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| thyroid mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| arthralgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 2 / 333 (0.60%) |
| occurrences (all) | 0 | 1 | 2 |
| arthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| arthropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| axillary mass | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| back pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 4 / 861 (0.46%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| bursitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cervical spinal stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chondrocalcinosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| chondropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| costochondritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| dactylitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| enthesopathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| exostosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| fibromyalgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| flank pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| groin pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| haemarthrosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intervertebral disc degeneration | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intervertebral disc disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intervertebral disc protrusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| intervertebral disc space narrowing | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint effusion | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint stiffness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| joint swelling | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ligament disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ligament pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lumbar spinal stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle contracture | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| muscle spasms | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| muscle tightness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| musculoskeletal chest pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| musculoskeletal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| myalgia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| musculoskeletal stiffness | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| myositis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| neck pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| osteoarthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| osteopenia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| osteoporosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pain in extremity | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| pain in jaw | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| patellofemoral pain syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| periarthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| plantar fasciitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| psoriatic arthropathy | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| rheumatic disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| rotator cuff syndrome | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| sacroiliitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| scoliosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spinal osteoarthritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spinal pain | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spinal retrolisthesis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| spondylolisthesis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| synovial cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| synovitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tendon disorder | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tendonitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tenosynovitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tenosynovitis stenosaurs | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| trigger finger | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vertebral foraminal stenosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| abdominal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| abscess jaw | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| abscess limb | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| acarodermatitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| acute sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| adenoviral conjunctivitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| appendicitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| appendicitis perforated | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|------------------|------------------|-----------------|
| asymptomatic covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bacterial vaginosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[40] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| body tinea | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| bronchitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| bronchitis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 16 / 453 (3.53%) | 11 / 861 (1.28%) | 6 / 333 (1.80%) |
| occurrences (all) | 16 | 11 | 6 |
| covid-19 pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| candida infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cellulitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| chronic sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctivitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctivitis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| conjunctivitis viral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronavirus infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| coronavirus pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cystitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| cystitis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| dermatophytosis of nail | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| diverticulitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ear infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| endocarditis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| enterococcal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| epididymitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[41] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| erysipelas | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| erythema migrans | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| erythrasma | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| folliculitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 1 | 1 |
| fungus infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| fungus skin infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| furuncle | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastroenteritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| gastroenteritis norovirus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastroenteritis bacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastroenteritis viral | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| gastrointestinal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gastrointestinal viral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| genital candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| genital herpes | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| genital herpes simplex | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| genital infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gingivitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| helicobacter infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hepatitis a | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| herpangina | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| herpes simplex | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| herpes zoster | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| herpes zoster infection neurological | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| histoplasmosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hordeolum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| impetigo | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| infected cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| influenza | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 1 | 0 | 1 |
| injection site infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| intervertebral discitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| laryngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| latent tuberculosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| localised infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| lower respiratory tract infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lyme disease | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| lymphogranuloma venereum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|------------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| molluscum contagiosum | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mucocutaneous candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| mycobacterial infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| myringitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| nasopharyngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 453 (1.10%) | 11 / 861 (1.28%) | 5 / 333 (1.50%) |
| occurrences (all) | 5 | 11 | 5 |
| onychomycosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ophthalmic herpes simplex | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| oral fungal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oral herpes | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| oral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| oropharyngeal candidiasis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| otitis media | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| otitis externa | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| papilloma viral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| paronychia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| parotitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pericoronitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| perineal abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| periodontitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pharyngitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pharyngitis streptococcal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pharyngotonsillitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| pilonidal cyst | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| pneumonia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| post procedural infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| postoperative wound infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| pulpitis dental alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| rash pustular alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| respiratory tract infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 1 / 861 (0.12%) 1 | 0 / 333 (0.00%) 0 |
| respiratory tract infection viral alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| rhinitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 1 / 861 (0.12%) 1 | 0 / 333 (0.00%) 0 |
| rhinovirus infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| root canal infection alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| salmonellosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| sinusitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 2 / 333 (0.60%) |
| occurrences (all) | 1 | 0 | 2 |
| skin candida | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| skin infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| soft tissue infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| subcutaneous abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| superinfection mycobacterial | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| superinfection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| suspected covid-19 | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| testicular abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[42] | 0 / 323 (0.00%) | 0 / 602 (0.00%) | 0 / 244 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea cruris | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tinea pedis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| tinea versicolour | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tonsillitis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tooth abscess | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| tooth infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| trichophytosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| tuberculosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| upper respiratory tract infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 5 / 453 (1.10%) | 5 / 861 (0.58%) | 4 / 333 (1.20%) |
| occurrences (all) | 5 | 5 | 4 |
| urethritis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| urinary tract infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 5 / 861 (0.58%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 6 | 1 |
| urinary tract infection enterococcal | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vaginal infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed ^[43] | 0 / 130 (0.00%) | 0 / 259 (0.00%) | 0 / 89 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| viral infection | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|----------------------|----------------------|
| viral sinusitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| viral upper respiratory tract infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 2 / 861 (0.23%) 2 | 0 / 333 (0.00%) 0 |
| vulvovaginal candidiasis alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[44] occurrences (all) | 0 / 130 (0.00%) 0 | 0 / 259 (0.00%) 0 | 0 / 89 (0.00%) 0 |
| vulvovaginal mycotic infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[45] occurrences (all) | 0 / 130 (0.00%) 0 | 0 / 259 (0.00%) 0 | 0 / 89 (0.00%) 0 |
| vulvovaginitis alternative dictionary used: MedDRA 24.1 subjects affected / exposed ^[46] occurrences (all) | 0 / 130 (0.00%) 0 | 0 / 259 (0.00%) 0 | 0 / 89 (0.00%) 0 |
| wound infection alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| Metabolism and nutrition disorders abnormal weight gain alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 0 / 453 (0.00%) 0 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| decreased appetite alternative dictionary used: MedDRA 24.1 subjects affected / exposed occurrences (all) | 1 / 453 (0.22%) 1 | 0 / 861 (0.00%) 0 | 0 / 333 (0.00%) 0 |
| diabetes mellitus alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 2 / 333 (0.60%) |
| occurrences (all) | 1 | 0 | 2 |
| dyslipidaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| glucose tolerance impaired | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| gout | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hypercalcaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| hypercholesterolaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperglycaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hyperkalaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hyperlipidaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| hypernatraemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 1 / 333 (0.30%) |
| occurrences (all) | 0 | 0 | 1 |
| hypertriglyceridaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 2 / 861 (0.23%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| hyperuricaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| hypokalaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hypomagnesaemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 1 / 453 (0.22%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| hyponatraemia | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| hypovitaminosis | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| impaired fasting glucose | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| insulin resistance | | | |
| alternative dictionary used: MedDRA 24.1 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| iron deficiency | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| overweight | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| type 2 diabetes mellitus | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 1 / 861 (0.12%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| underweight | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vitamin b12 deficiency | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| vitamin d deficiency | | | |
| alternative dictionary used: MedDRA 24.1 | | | |
| subjects affected / exposed | 0 / 453 (0.00%) | 0 / 861 (0.00%) | 0 / 333 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

Notes:

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

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

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

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

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

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

[45] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

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

Justification: Gender specific events only occurring in male or female participants have had the number of participants at risk adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 15 November 2018 | - Modified schedule of activities, clinical laboratory tests, inclusion criteria and immunogenicity assessments sections; -Added ability for participants to receive psoriasis therapy with another agent(s) in post-treatment follow-up period; - Text clarified in blinding details; - Stricter discontinuation language for clinically significant systemic hypersensitivity events has been applied throughout the protocol; - Added expectation on timing of clinical assessments of tuberculosis (TB) risk. |

Notes:

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.

| |
|---|
| This study was terminated before completion of the long-term extension trial, due to strategic business decision made by the company. |
|---|

Notes: