



Clinical trial results:

A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer

Summary

| | |
|--------------------------|----------------------------|
| EudraCT number | 2008-008004-41 |
| Trial protocol | GB NL SE FR DE BE ES IT GR |
| Global end of trial date | 25 May 2017 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 09 June 2018 |
| First version publication date | 09 June 2018 |

Trial information

Trial identification

| | |
|-----------------------|------------|
| Sponsor protocol code | COU-AA-302 |
|-----------------------|------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00887198 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Janssen Research & Development, LLC |
| Sponsor organisation address | 1000 U.S. Route 202 South, Raritan, NJ, United States, 08869 |
| Public contact | Clinical Registry group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Clinical Registry group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 31 March 2014 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 25 May 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to compare the clinical benefit of abiraterone acetate plus prednisone to placebo plus prednisone in men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC), who were asymptomatic or mildly symptomatic.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Known instances of nonconformance were documented and are not considered to have had an impact on the overall conclusions of this study. Safety was evaluated throughout the study and included adverse events (AEs), serious adverse events (SAEs), routine chemical test (Hematology, chemistry, coagulation, urinalysis and Serum Lipids), vital signs, Electrocardiograms, Physical examinations and body weight.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 28 April 2009 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 132 |
| Country: Number of subjects enrolled | Belgium: 42 |
| Country: Number of subjects enrolled | Canada: 100 |
| Country: Number of subjects enrolled | France: 53 |
| Country: Number of subjects enrolled | Germany: 78 |
| Country: Number of subjects enrolled | Greece: 14 |
| Country: Number of subjects enrolled | Italy: 7 |
| Country: Number of subjects enrolled | Netherlands: 30 |
| Country: Number of subjects enrolled | Spain: 45 |
| Country: Number of subjects enrolled | Sweden: 17 |
| Country: Number of subjects enrolled | United Kingdom: 98 |
| Country: Number of subjects enrolled | United States: 472 |
| Worldwide total number of subjects | 1088 |
| EEA total number of subjects | 384 |

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) | 290 |
| From 65 to 84 years | 741 |
| 85 years and over | 57 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 1088 subjects were randomized out of which 1082 (542 in Abiraterone Acetate [AA] group and 540 in placebo group) received the study drug. After Amendment 3, subjects receiving placebo and after amendment 4 those who were discontinued from placebo, but continuing in long-term follow up were crossed over to abiraterone acetate treatment.

Period 1

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

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | Abiraterone Acetate + Prednisone (AAP) |

Arm description:

Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

| | |
|--|---------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Abiraterone Acetate |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily.

| | |
|--|------------|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects received prednisone 5 mg tablet orally twice daily, from Day 1 along with 1000 mg abiraterone acetate tablets (as 4*250 mg tablets) orally once daily.

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

Arm description:

Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

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

Dosage and administration details:

Subjects received 4 tablets of placebo matching to Abiraterone Acetate 250 mg orally along with prednisone 5 mg tablet orally twice daily.

| | |
|--|------------|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects received prednisone 5 mg tablet orally twice daily, from Day 1 along with 1000 mg abiraterone acetate tablets (as 4*250 mg tablets) orally once daily.

| Number of subjects in period 1 | Abiraterone Acetate + Prednisone (AAP) | Placebo |
|---------------------------------------|---|----------------|
| Started | 546 | 542 |
| Treated | 542 | 540 |
| Total crossover to AA | 0 | 93 |
| Completed | 0 | 0 |
| Not completed | 546 | 542 |
| Consent withdrawn by subject | 41 | 56 |
| Cross-over to aa | - | 51 |
| Lost to follow-up | 1 | - |
| Adverse event, non-fatal | 50 | 33 |
| Randomized, Not treated | 4 | 2 |
| Ongoing | 42 | - |
| Unspecified | 42 | 30 |
| Progressive disease | 366 | 370 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Abiraterone Acetate + Prednisone (AAP) |
|-----------------------|--|

Reporting group description:

Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

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

Reporting group description:

Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

| Reporting group values | Abiraterone Acetate + Prednisone (AAP) | Placebo | Total |
|---|--|---------|-------|
| Number of subjects | 546 | 542 | 1088 |
| Title for AgeCategorical Units: subjects | | | |
| Adults (18-64 years) | 135 | 155 | 290 |
| From 65 to 84 years | 383 | 358 | 741 |
| 85 years and over | 28 | 29 | 57 |
| Title for AgeContinuous Units: years | | | |
| arithmetic mean | 70.5 | 70.1 | |
| standard deviation | ± 8.8 | ± 8.72 | - |
| Title for Gender Units: subjects | | | |
| Male | 546 | 542 | 1088 |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | Abiraterone Acetate + Prednisone (AAP) |
| Reporting group description: Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression. | |
| Reporting group title | Placebo |
| Reporting group description: Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression. | |
| Subject analysis set title | Placebo to Abiraterone Acetate (AA) |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: Subjects who were originally assigned to placebo were later on switched to 1,000 milligram (mg) abiraterone acetate tablet (as 4*250 mg tablets) along with prednisone 5 mg tablet. | |

Primary: Overall Survival

| | |
|---|------------------|
| End point title | Overall Survival |
| End point description: Overall survival is defined as the time from randomization to date of death from any cause. Intent-to-treat (ITT) population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received. | |
| End point type | Primary |
| End point timeframe: From randomization (Day 1) up to end of study (Month 60) | |

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|----------------------------------|--|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 546 | 542 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 34.66 (32.72 to 36.80) | 30.29 (28.65 to 33.28) | | |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Abiraterone Acetate + Prednisone (AAP) v Placebo |

| | |
|---|-------------------|
| Number of subjects included in analysis | 1088 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0033 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.806 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.697 |
| upper limit | 0.931 |

Primary: Radiographic Progression-free Survival (rPFS)

| | |
|--|---|
| End point title | Radiographic Progression-free Survival (rPFS) |
| End point description: | |
| <p>The rPFS was defined as time from randomization to the occurrence of one of the following a subject was considered to have progressed by bone scan if a) the first bone scan with ≥ 2 new lesions compared to baseline was observed in less than ($<$) 12 weeks from randomization and was confirmed by a second bone scan taken ≥ 6 weeks later showing ≥ 2 additional new lesions (a total of ≥ 4 new lesions compared to baseline), b) the first bone scan with ≥ 2 new lesions compared to baseline was observed in ≥ 12 weeks from randomization and the new lesions were verified on the next bone scan ≥ 6 weeks later; 2) progression of soft tissue lesions measured by computerized tomography (CT) or MRI 3) death from any cause. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received. Here "99999" indicates data was not estimable due to insufficient number of subjects who had the event.</p> | |
| End point type | Primary |
| End point timeframe: | |
| From randomization (Day 1) up to first radiographic progression or cutoff date (Month 18) | |

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|----------------------------------|--|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 546 | 542 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 99999 (11.66 to 99999) | 8.28 (8.12 to 8.54) | | |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Statistical analysis 1 |
| Comparison groups | Abiraterone Acetate + Prednisone (AAP) v Placebo |

| | |
|---|-------------------|
| Number of subjects included in analysis | 1088 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Logrank |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.425 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.347 |
| upper limit | 0.522 |

Secondary: Time to Opiate Use for Prostate Cancer Pain

| | |
|--|---|
| End point title | Time to Opiate Use for Prostate Cancer Pain |
| End point description: | |
| The time interval from the date of randomization to the date of opiate use for cancer pain. Subjects who have no opiate use at the time of analysis were censored at the last known date of no opiate use for cancer pain. Subjects with no assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received. | |
| End point type | Secondary |
| End point timeframe: | |
| From randomization (Day 1) up to first opiate use or end of study (Month 60) | |

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|----------------------------------|--|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 546 | 542 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 33.28 (30.23 to 39.75) | 23.39 (20.27 to 27.53) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Initiation of Cytotoxic Chemotherapy

| | |
|---|--|
| End point title | Time to Initiation of Cytotoxic Chemotherapy |
| End point description: | |
| The time interval from the date of randomization to the date of initiation of cytotoxic chemotherapy for prostate cancer. Subjects who had no cytotoxic chemotherapy administration at the time of analysis were censored at the last known date when no cytotoxic chemotherapy was administered. Subjects with no assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual | |

treatment received. Here "99999" indicates data was not estimable due to insufficient number of subjects who had the event.

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

End point timeframe:

From randomization (Day 1) up to initiation of cytotoxic chemotherapy or cutoff date (Month 18)

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|----------------------------------|--|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 546 | 542 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 25.17 (23.26 to 99999) | 16.82 (14.55 to 19.38) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Deterioration in Eastern Cooperative Oncology Group (ECOG) Performance Score by ≥ 1 Point

| | |
|-----------------|--|
| End point title | Time to Deterioration in Eastern Cooperative Oncology Group (ECOG) Performance Score by ≥ 1 Point |
|-----------------|--|

End point description:

The time interval from the date of randomization to the first date at which there was at least a 1 grade change (worsening) in the ECOG performance status grade. Subjects who had no deterioration in ECOG performance status grade at the time of the analysis were censored at the last known date of no deterioration. ECOG is a 5-point scale, where 0=Fully active, 1=Ambulatory, carry out work of sedentary nature, 2=Ambulatory, capable of all self-care, 3=Capable of limited self-care, confined to bed or chair more than 50% of waking hours, 4=Completely disabled, no self-care, totally confined to bed or chair, 5=Dead. Subjects with no assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received.

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

End point timeframe:

From randomization (Day 1) up to first radiographic progression or cutoff date (Month 18)

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|----------------------------------|--|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 546 | 542 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 12.29 (11.33 to 14.29) | 10.87 (9.49 to 11.76) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Prostate-specific Antigen (PSA) Progression

| | |
|-----------------|---|
| End point title | Time to Prostate-specific Antigen (PSA) Progression |
|-----------------|---|

End point description:

The time interval from the date of randomization to the date of PSA progression as defined in the protocol-specific prostate cancer Working Group 2 (PCWG2) criteria. A subjects was considered to have a PSA progression if the PSA level had a 25 percent (%) or greater increase from nadir and an absolute increase of 2 nanogram/milliliter ((ng/mL) or more, which is confirmed by a second value obtained in 3 or more weeks. Subjects who had no PSA progression at the time of the analysis were censored at the last known date of no PSA progression. Subjects with no on-study PSA assessment or no baseline PSA assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received.

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

End point timeframe:

From randomization (Day 1) up to date of PSA progerssion or cutoff date (Month 18)

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|----------------------------------|---|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 546 | 542 | | |
| Units: Months | | | | |
| median (confidence interval 95%) | 11.07 (8.51 to 11.24) | 5.55 (5.39 to 5.59) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events

| | |
|-----------------|---|
| End point title | Number of Subjects With Treatment Emergent Adverse Events |
|-----------------|---|

End point description:

An adverse event (AE) was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. A serious adverse event (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between administration of study drug and up to 30 days after last dose of study drug that were absent before treatment or that worsened relative to pre-treatment state. Safety analysis set included all subjects in the randomized population who received any study drug.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From first dose of study drug up to 30 days after the last dose of study drug | |

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | Placebo to Abiraterone Acetate (AA) | |
|--|--|-----------------|-------------------------------------|--|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 542 | 540 | 93 | |
| Units: Subjects | | | | |
| With Treatment-Emergent Adverse Events | 541 | 524 | 93 | |
| With Treatment-Emergent Serious Adverse Events | 208 | 148 | 39 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Plasma Concentrations of Abiraterone

| | |
|------------------------|---|
| End point title | Mean Plasma Concentrations of Abiraterone |
| End point description: | |

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to Cycle 5, Day 1 | |

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|--|--|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[1] | 0 ^[2] | | |
| Units: nanogram per milliliter (ng/ml) | | | | |
| arithmetic mean (standard deviation) | () | () | | |

Notes:

[1] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[2] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Plasma Concentrations of Abiraterone

| | |
|-----------------|--|
| End point title | Maximum Plasma Concentrations of Abiraterone |
|-----------------|--|

End point description:

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

End point timeframe:

Up to Cycle 5, Day 1

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|--|--|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[3] | 0 ^[4] | | |
| Units: nanogram per milliliter (ng/ml) | | | | |
| arithmetic mean (standard deviation) | () | () | | |

Notes:

[3] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[4] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve from Time 0 to Time the Last Quantifiable Concentration of Abiraterone (AUC[0-infinity])

| | |
|-----------------|---|
| End point title | Area Under the Plasma Concentration-time Curve from Time 0 to Time the Last Quantifiable Concentration of Abiraterone (AUC[0-infinity]) |
|-----------------|---|

End point description:

The AUC (0-infinity) is the area under the plasma concentration-time curve from time zero to infinite time, calculated as the sum of AUC(last) and C(last)/lambda(z); wherein AUC(last) is area under the plasma concentration-time curve from time zero to last quantifiable time, C(last) is the last observed quantifiable concentration, and lambda(z) is elimination rate constant.

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

End point timeframe:

Up to Cycle 5, Day 1

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|--------------------------------------|--|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[5] | 0 ^[6] | | |
| Units: nanogram*hour per milliliter | | | | |
| arithmetic mean (standard deviation) | () | () | | |

Notes:

[5] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[6] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Elimination Half-Life (t1/2)

| | |
|-----------------|------------------------------|
| End point title | Elimination Half-Life (t1/2) |
|-----------------|------------------------------|

End point description:

The elimination half-life (t1/2) is the time measured for the plasma concentration to decrease by 1 half to its original concentration. It is associated with the terminal slope of the semi logarithmic drug concentration-time curve, and is calculated as $0.693/\lambda(z)$.

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

End point timeframe:

Up to Cycle 5, Day 1

| End point values | Abiraterone Acetate + Prednisone (AAP) | Placebo | | |
|--------------------------------------|--|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0 ^[7] | 0 ^[8] | | |
| Units: Hours | | | | |
| arithmetic mean (standard deviation) | () | () | | |

Notes:

[7] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[8] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug up to 30 days after the last dose of study drug

Adverse event reporting additional description:

Safety analysis set included all subjects in the randomized population who received any study drug.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 11.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Abiraterone Acetate + Prednisone (AAP) |
|-----------------------|--|

Reporting group description:

Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

| | |
|-----------------------|---------------|
| Reporting group title | Placebo to AA |
|-----------------------|---------------|

Reporting group description:

Subjects who were originally assigned to placebo were later on switched to 1,000 milligram (mg) abiraterone acetate tablet (as 4*250 mg tablets) along with prednisone 5 mg tablet.

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

Reporting group description:

Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

| Serious adverse events | Abiraterone Acetate + Prednisone (AAP) | Placebo to AA | Placebo |
|---|--|------------------|--------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 215 / 542 (39.67%) | 40 / 93 (43.01%) | 156 / 540 (28.89%) |
| number of deaths (all causes) | 352 | 24 | 387 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| B-Cell Type Acute Leukaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Bladder Cancer | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Bladder Transitional Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Cancer Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Central Nervous System Lymphoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic Lymphocytic Leukaemia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Colon Adenoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Colorectal Cancer | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 Cancer | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Neoplasm | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 Neoplasm Malignant | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Malignant Melanoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant Neoplasm of Ampulla of Vater | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to Meninges | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastatic Pain | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Pancreatic Carcinoma | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Urethral Cancer | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Arterial Thrombosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| 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 | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolism Venous | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertensive Crisis | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Orthostatic Hypotension | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral Embolism | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral Vascular Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Thrombophlebitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Venous Thrombosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| Aortic Valve Replacement | | | |

| | | | |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Chemotherapy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Knee Arthroplasty | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Pancreatectomy | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Transurethral Prostatectomy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Catheter Related Complication | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Death | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Disease Progression | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 6 / 93 (6.45%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 1 / 8 | 0 / 6 | 0 / 4 |
| deaths causally related to treatment / all | 1 / 5 | 0 / 3 | 0 / 2 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 2 / 93 (2.15%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gait Disturbance | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General Physical Health Deterioration | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 1 |
| Hypothermia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Malaise | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mucosal Inflammation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Multi-Organ Failure | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 2 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema Peripheral | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Performance Status Decreased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Pyrexia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Systemic Inflammatory Response Syndrome | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Reproductive system and breast disorders | | | |
| Erectile Dysfunction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Prostatic Haemorrhage | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Prostatomegaly | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Scrotal Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| 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 | | | |
| Acute Pulmonary Oedema | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic Obstructive Pulmonary Disease | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Dyspnoea | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 6 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Hypoxia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural Effusion | | | |

| | | | |
|---|------------------|----------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 2 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Aspiration | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Pneumothorax | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 1 / 93 (1.08%) | 12 / 540 (2.22%) |
| occurrences causally related to treatment / all | 4 / 10 | 0 / 2 | 4 / 12 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Failure | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Tonsillar Cyst | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Psychiatric disorders | | | |
| Agitation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Completed Suicide | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Confusional State | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Investigations | | | |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 5 / 5 | 0 / 0 | 3 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate Aminotransferase Increased | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Blood Uric Acid Increased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Colonoscopy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Electrocardiogram QT Prolonged | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Electrocardiogram St Segment Depression | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Lipase Increased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Platelet Count Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Injury, poisoning and procedural complications | | | |
| Animal Scratch | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Ankle Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bladder Perforation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract Operation Complication | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cystitis Radiation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Device Dislocation | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Fall | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femoral Neck Fracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur Fracture | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Radiation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal Anastomotic Leak | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Implantable Defibrillator Malfunction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Multiple Fractures | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Multiple Injuries | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Narcotic Intoxication | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Procedural Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pubic Rami Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scapula Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Skeletal Injury | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin Laceration | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Skull Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Soft Tissue Injury | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Stress Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Subdural Haematoma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 2 / 93 (2.15%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Subdural Haemorrhage | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tendon Rupture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tibia Fracture | | | |

| | | | |
|---|------------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Cardiac disorders | | | |
| Acute Coronary Syndrome | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Acute Myocardial Infarction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Angina Pectoris | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 3 / 6 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 0 / 93 (0.00%) | 8 / 540 (1.48%) |
| occurrences causally related to treatment / all | 5 / 13 | 0 / 0 | 7 / 8 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Atrioventricular Block | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrioventricular Block Second Degree | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Bifascicular Block | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Cardiac Arrest | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| Cardiac Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac Failure | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Cardiac Failure Congestive | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Conduction Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 2 / 4 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Ischaemic Cardiomyopathy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Myocardial Infarction | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 4 / 542 (0.74%) | 2 / 93 (2.15%) | 5 / 540 (0.93%) |
| occurrences causally related to treatment / all | 2 / 4 | 0 / 2 | 2 / 5 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 1 |
| Myocardial Ischaemia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Supraventricular Tachyarrhythmia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Supraventricular Tachycardia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tachyarrhythmia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Amyotrophic Lateral Sclerosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral Haemorrhage | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral Infarction | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Cerebral Ischaemia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 3 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular Accident | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | 1 / 1 |
| Convulsion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Dizziness | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolic Stroke | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Memory Impairment | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Migraine with Aura | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Monoparesis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nerve Root Compression | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Neurological Symptom | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Paraparesis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Paraplegia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Presyncope | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Quadripareisis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal Cord Compression | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | 1 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope Vasovagal | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vith Nerve Paralysis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 8 / 542 (1.48%) | 1 / 93 (1.08%) | 6 / 540 (1.11%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 1 | 6 / 9 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coagulopathy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Disseminated Intravascular Coagulation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Febrile Neutropenia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Hypoacusis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Gastrointestinal disorders | | | |
| Abdominal Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 2 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain Lower | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Colitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticular Perforation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Diverticulum Intestinal | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Diverticulum Intestinal Haemorrhagic | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovesical Fistula | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Food Poisoning | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| 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 Ulcer | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Gastritis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Gastritis Erosive | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal Haemorrhage | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal Necrosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal Ischaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Intestinal Obstruction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Melaena | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Nausea | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophageal Mass | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Pancreatic Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis Necrotising | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Periodontitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Varices Oesophageal | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Bile Duct Obstruction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Jaundice | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Actinic Keratosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Lentigo | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin Lesion | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Renal and urinary disorders | | | |
| Bladder Mass | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Bladder Obstruction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bladder Spasm | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bladder Tamponade | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Calculus Bladder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 2 / 93 (2.15%) | 0 / 540 (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 |
| Calculus Ureteric | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematuria | | | |

| | | | |
|---|------------------|----------------|-----------------|
| subjects affected / exposed | 11 / 542 (2.03%) | 3 / 93 (3.23%) | 5 / 540 (0.93%) |
| occurrences causally related to treatment / all | 1 / 14 | 0 / 3 | 1 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhage Urinary Tract | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Hydronephrosis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Obstructive Uropathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Colic | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Failure | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Failure Acute | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Impairment | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Ureteric Obstruction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ureteric Stenosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urethral Obstruction | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urethral Stenosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary Incontinence | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary Retention | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary Tract Obstruction | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal Insufficiency | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 1 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Back Pain | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 1 | 2 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bone Pain | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | 1 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Flank Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|----------------|-----------------|
| Groin Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Jaw Cyst | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Joint Swelling | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Lumbar Spinal Stenosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Muscular Weakness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteoarthritis | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteonecrosis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in Extremity | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 2 / 93 (2.15%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pathological Fracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotator Cuff Syndrome | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Spinal Column Stenosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis Bacterial | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Bacteraemia | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary Sepsis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis Infective | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Cellulitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 2 / 93 (2.15%) | 3 / 540 (0.56%) |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 3 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cystitis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterococcal Infection | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Escherichia Urinary Tract Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder Abscess | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Salmonella | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Gingival Infection | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes Zoster | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Infected Skin Ulcer | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Infective Exacerbation of Chronic Obstructive Airways Disease | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Influenza | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower Respiratory Tract Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung Infection | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Necrotising Fasciitis | | | |

| | | | |
|---|------------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Parainfluenzae Virus Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Pneumonia | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 3 / 12 | 0 / 1 | 2 / 4 |
| deaths causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| Pneumonia Influenzal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Staphylococcal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Pseudomonal Bacteraemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis | | | |

| | | | |
|---|------------------|----------------|-----------------|
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Tract Infection | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 2 / 8 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 5 / 93 (5.38%) | 4 / 540 (0.74%) |
| occurrences causally related to treatment / all | 8 / 17 | 0 / 8 | 1 / 5 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 0 |
| Urinary Tract Infection Bacterial | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urosepsis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wound Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (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 |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Dehydration | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to Thrive | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (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 |
| Fluid Retention | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | Abiraterone Acetate + Prednisone (AAP) | Placebo to AA | Placebo |
|---|--|------------------|--------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 540 / 542 (99.63%) | 88 / 93 (94.62%) | 524 / 540 (97.04%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acoustic Neuroma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Acrochordon | | | |

| | | | |
|-------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 2 | 0 | 4 |
| Atypical Fibroxanthoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Basal Cell Carcinoma | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 2 / 93 (2.15%) | 10 / 540 (1.85%) |
| occurrences (all) | 10 | 2 | 13 |
| Benign Neoplasm of Skin | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bladder Neoplasm | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bowen's Disease | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cancer Pain | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 0 / 93 (0.00%) | 16 / 540 (2.96%) |
| occurrences (all) | 18 | 0 | 26 |
| Chronic Lymphocytic Leukaemia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Colon Adenoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Cystic Lymphangioma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemangioma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Keratoacanthoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 4 |
| Lip Neoplasm Malignant Stage | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Unspecified | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lipoma | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 1 | 3 |
| Malignant Melanoma | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Melanocytic Naevus | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 1 | 1 |
| Metastases to Bone | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Metastatic Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Neoplasm Malignant | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Neurilemmoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rectal Cancer | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Renal Cell Carcinoma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Seborrhoeic Keratosis | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 7 | 0 | 4 |
| Skin Papilloma | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 3 | 0 | 4 |

| | | | |
|---|------------------|----------------|-----------------|
| Spinal Cord Neoplasm | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Squamous Cell Carcinoma | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 16 | 3 | 4 |
| Squamous Cell Carcinoma of Skin | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tongue Neoplasm Malignant Stage Unspecified | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Transitional Cell Carcinoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Tumour Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Vocal Cord Neoplasm | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular disorders | | | |
| Angiodysplasia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aortic Aneurysm | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aortic Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Arterial Thrombosis Limb | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Capillary Fragility | | | |

| | | | |
|---|--------------------|----------------|--------------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Circulatory Collapse | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Deep Vein Thrombosis | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 1 / 93 (1.08%) | 6 / 540 (1.11%) |
| occurrences (all) | 8 | 1 | 6 |
| Flushing | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 9 | 0 | 5 |
| Gastrointestinal Arteriovenous Malformation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematoma | | | |
| subjects affected / exposed | 22 / 542 (4.06%) | 1 / 93 (1.08%) | 6 / 540 (1.11%) |
| occurrences (all) | 32 | 1 | 6 |
| Haemorrhage | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hot Flush | | | |
| subjects affected / exposed | 124 / 542 (22.88%) | 6 / 93 (6.45%) | 100 / 540 (18.52%) |
| occurrences (all) | 153 | 6 | 122 |
| Hypertension | | | |
| subjects affected / exposed | 129 / 542 (23.80%) | 6 / 93 (6.45%) | 73 / 540 (13.52%) |
| occurrences (all) | 182 | 8 | 94 |
| Hypotension | | | |
| subjects affected / exposed | 24 / 542 (4.43%) | 3 / 93 (3.23%) | 16 / 540 (2.96%) |
| occurrences (all) | 24 | 4 | 19 |
| Intermittent Claudication | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Lymphoedema | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |

| | | | |
|------------------------------|-----------------|----------------|-----------------|
| Microangiopathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Orthostatic Hypotension | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 2 / 93 (2.15%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 2 | 4 |
| Pallor | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Peripheral Ischaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Peripheral Vascular Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Phlebitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Thrombophlebitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Thrombophlebitis Superficial | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Thrombosis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Varicose Vein | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 1 | 0 | 4 |
| Vein Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Venous Thrombosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|------------------------|---------------------|------------------------|
| Venous Thrombosis Limb subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Surgical and medical procedures | | | |
| Cataract Operation subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 2 |
| Knee Arthroplasty subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Skin Neoplasm Excision subjects affected / exposed occurrences (all) | 2 / 542 (0.37%) 2 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Transurethral Prostatectomy subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Ureteral Stent Insertion subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Wisdom Teeth Removal subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| General disorders and administration site conditions | | | |
| Abasia subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Adverse Drug Reaction subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 2 / 540 (0.37%) 2 |
| Asthenia subjects affected / exposed occurrences (all) | 46 / 542 (8.49%) 65 | 1 / 93 (1.08%) 1 | 46 / 540 (8.52%) 66 |
| Axillary Pain subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 2 / 540 (0.37%) 2 |
| Catheter Related Complication | | | |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 0 | 0 | 7 |
| Catheter Site Erythema | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Catheter Site Haematoma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Catheter Site Haemorrhage | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Catheter Site Inflammation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Catheter Site Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 8 |
| Chest Discomfort | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 10 | 0 | 8 |
| Chest Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 2 | 1 | 8 |
| Chills | | | |
| subjects affected / exposed | 15 / 542 (2.77%) | 2 / 93 (2.15%) | 14 / 540 (2.59%) |
| occurrences (all) | 17 | 2 | 17 |
| Cyst | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 2 |
| Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Disease Progression | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 2 / 93 (2.15%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 2 | 1 |
| Energy Increased | | | |

| | | | |
|---------------------------------------|--------------------|------------------|--------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Extravasation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Face Oedema | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 6 | 0 | 4 |
| Facial Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 243 / 542 (44.83%) | 27 / 93 (29.03%) | 200 / 540 (37.04%) |
| occurrences (all) | 448 | 35 | 314 |
| Feeling Abnormal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Feeling Cold | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 1 | 1 |
| Feeling Hot | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 2 |
| Feeling Jittery | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 2 |
| Gait Disturbance | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 0 / 93 (0.00%) | 10 / 540 (1.85%) |
| occurrences (all) | 12 | 0 | 12 |
| General Physical Health Deterioration | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 8 | 0 | 3 |
| Generalised Oedema | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Hangover | | | |

| | | | |
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| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hernia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hernia Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Hunger | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperthermia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Hypothermia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Impaired Healing | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Implant Site Inflammation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Implant Site Reaction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Inflammation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Influenza Like Illness | | | |
| subjects affected / exposed | 20 / 542 (3.69%) | 4 / 93 (4.30%) | 10 / 540 (1.85%) |
| occurrences (all) | 27 | 4 | 14 |
| Infusion Site Bruising | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection Site Bruising | | | |

| | | | |
|-----------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Injection Site Haematoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection Site Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection Site Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection Site Reaction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 7 | 0 | 5 |
| Local Swelling | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Localised Oedema | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 5 | 0 | 1 |
| Malaise | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 12 | 0 | 7 |
| Mass | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 1 | 2 |
| Mucosal Inflammation | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 9 | 0 | 2 |
| Multi-Organ Failure | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nodule | | | |

| | | | |
|------------------------------|--------------------|------------------|--------------------|
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 6 | 0 | 1 |
| Non-Cardiac Chest Pain | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 13 | 1 | 14 |
| Oedema Peripheral | | | |
| subjects affected / exposed | 148 / 542 (27.31%) | 22 / 93 (23.66%) | 119 / 540 (22.04%) |
| occurrences (all) | 269 | 24 | 198 |
| Pain | | | |
| subjects affected / exposed | 27 / 542 (4.98%) | 0 / 93 (0.00%) | 16 / 540 (2.96%) |
| occurrences (all) | 28 | 0 | 18 |
| Papillitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pelvic Mass | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Performance Status Decreased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Peripheral Coldness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Pitting Oedema | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 4 | 0 | 6 |
| Puncture Site Reaction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 54 / 542 (9.96%) | 5 / 93 (5.38%) | 33 / 540 (6.11%) |
| occurrences (all) | 69 | 7 | 45 |
| Sensation of Pressure | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Suprapubic Pain | | | |

| | | | |
|---|----------------------|---------------------|----------------------|
| subjects affected / exposed occurrences (all) | 3 / 542 (0.55%) 3 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Temperature Intolerance subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 2 / 540 (0.37%) 2 |
| Thirst subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Venipuncture Site Swelling subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Vessel Puncture Site Haematoma subjects affected / exposed occurrences (all) | 2 / 542 (0.37%) 2 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Wound Necrosis subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 2 |
| Xerosis subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Immune system disorders Contrast Media Allergy subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 2 |
| Drug Hypersensitivity subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Hypersensitivity subjects affected / exposed occurrences (all) | 3 / 542 (0.55%) 3 | 0 / 93 (0.00%) 0 | 4 / 540 (0.74%) 4 |
| Seasonal Allergy subjects affected / exposed occurrences (all) | 7 / 542 (1.29%) 8 | 2 / 93 (2.15%) 2 | 5 / 540 (0.93%) 5 |
| Reproductive system and breast disorders | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Balanitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Breast Mass | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Breast Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Breast Tenderness | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 4 |
| Epididymal Cyst | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erectile Dysfunction | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 9 | 0 | 2 |
| Genital Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Nipple Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Oedema Genital | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Penile Discharge | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Penile Oedema | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Penile Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 6 | 0 | 2 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Penile Size Reduced | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Perineal Pain | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 0 | 3 |
| Prostate Induration | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Prostatic Obstruction | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Prostatic Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Prostatism | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Prostatitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Scrotal Haematocoele | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Scrotal Oedema | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Scrotal Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 1 | 1 |
| Testicular Atrophy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Testicular Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|----------------|-----------------|
| Testicular Pain | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 8 | 0 | 2 |
| Testicular Swelling | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 4 |
| Testis Discomfort | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asphyxia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Asthma | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 5 | 0 | 1 |
| Atelectasis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 0 | 3 |
| Bronchopneumopathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchospasm | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Chest Discomfort | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Chronic Obstructive Pulmonary Disease | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 2 / 93 (2.15%) | 4 / 540 (0.74%) |
| occurrences (all) | 4 | 2 | 4 |
| Cough | | | |

| | | | |
|----------------------------------|--------------------|------------------|-------------------|
| subjects affected / exposed | 106 / 542 (19.56%) | 11 / 93 (11.83%) | 74 / 540 (13.70%) |
| occurrences (all) | 146 | 14 | 92 |
| Dry Throat | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Dysphonia | | | |
| subjects affected / exposed | 17 / 542 (3.14%) | 0 / 93 (0.00%) | 6 / 540 (1.11%) |
| occurrences (all) | 18 | 0 | 6 |
| Dyspnoea | | | |
| subjects affected / exposed | 71 / 542 (13.10%) | 7 / 93 (7.53%) | 52 / 540 (9.63%) |
| occurrences (all) | 116 | 8 | 74 |
| Dyspnoea Exertional | | | |
| subjects affected / exposed | 16 / 542 (2.95%) | 0 / 93 (0.00%) | 13 / 540 (2.41%) |
| occurrences (all) | 21 | 0 | 13 |
| Emphysema | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 1 | 0 | 3 |
| Epistaxis | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 1 / 93 (1.08%) | 9 / 540 (1.67%) |
| occurrences (all) | 13 | 1 | 10 |
| Haemoptysis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Increased Bronchial Secretion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Increased Upper Airway Secretion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 3 |
| Interstitial Lung Disease | | | |

| | | | |
|--------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Lung Infiltration | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal Congestion | | | |
| subjects affected / exposed | 20 / 542 (3.69%) | 0 / 93 (0.00%) | 14 / 540 (2.59%) |
| occurrences (all) | 26 | 0 | 18 |
| Nasal Mucosal Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasal Septum Deviation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Orthopnoea | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Paranasal Sinus Hypersecretion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngeal Erythema | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngolaryngeal Discomfort | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Pharyngolaryngeal Pain | | | |
| subjects affected / exposed | 21 / 542 (3.87%) | 4 / 93 (4.30%) | 13 / 540 (2.41%) |
| occurrences (all) | 29 | 4 | 14 |
| Pleural Effusion | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 0 | 3 |
| Pleuritic Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Pneumonia Aspiration | | | |

| | | | |
|------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Postnasal Drip | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 0 | 3 |
| Productive Cough | | | |
| subjects affected / exposed | 17 / 542 (3.14%) | 0 / 93 (0.00%) | 11 / 540 (2.04%) |
| occurrences (all) | 23 | 0 | 13 |
| Prolonged Expiration | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 8 / 540 (1.48%) |
| occurrences (all) | 5 | 0 | 9 |
| Pulmonary Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary Hypertension | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Rales | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 4 | 0 | 4 |
| Respiratory Distress | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Respiratory Failure | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Respiratory Tract Congestion | | | |

| | | | |
|-------------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 10 / 542 (1.85%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 14 | 0 | 4 |
| Respiratory Tract Haemorrhage | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 12 | 0 | 4 |
| Rhinitis Allergic | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 0 / 93 (0.00%) | 9 / 540 (1.67%) |
| occurrences (all) | 14 | 0 | 9 |
| Rhonchi | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Sinus Congestion | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences (all) | 21 | 1 | 4 |
| Sinus Polyp | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sleep Apnoea Syndrome | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Sputum Discoloured | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Throat Irritation | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tracheal Pain | | | |

| | | | |
|------------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper Respiratory Tract Congestion | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Wheezing | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 2 / 93 (2.15%) | 7 / 540 (1.30%) |
| occurrences (all) | 9 | 2 | 7 |
| Psychiatric disorders | | | |
| Abnormal Dreams | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Affect Lability | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Affective Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Aggression | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Agitation | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 4 | 0 | 6 |
| Alcoholism | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Anxiety | | | |
| subjects affected / exposed | 30 / 542 (5.54%) | 4 / 93 (4.30%) | 23 / 540 (4.26%) |
| occurrences (all) | 38 | 4 | 25 |
| Bipolar Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bulimia Nervosa | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|-------------------|----------------|-------------------|
| Claustrophobia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Confusional State | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 2 / 93 (2.15%) | 10 / 540 (1.85%) |
| occurrences (all) | 7 | 2 | 13 |
| Delirium | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Depressed Mood | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 16 | 1 | 8 |
| Depression | | | |
| subjects affected / exposed | 32 / 542 (5.90%) | 3 / 93 (3.23%) | 19 / 540 (3.52%) |
| occurrences (all) | 41 | 3 | 20 |
| Disorientation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Elevated Mood | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Emotional Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hallucination, Visual | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Impatience | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Insomnia | | | |
| subjects affected / exposed | 82 / 542 (15.13%) | 5 / 93 (5.38%) | 62 / 540 (11.48%) |
| occurrences (all) | 112 | 5 | 67 |
| Libido Decreased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |

| | | | |
|--|-----------------|----------------|-----------------|
| Loss of Libido | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Mania | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Mental Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mental Disorder Due to A General Medical Condition | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Middle Insomnia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mood Altered | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 8 / 540 (1.48%) |
| occurrences (all) | 9 | 0 | 8 |
| Mood Swings | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 1 | 0 | 4 |
| Nervousness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Panic Attack | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pressure of Speech | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Restlessness | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Seasonal Affective Disorder | | | |

| | | | |
|---|-------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Sleep Disorder | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 6 | 1 | 7 |
| Somnambulism | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stress | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Suicidal Ideation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Suspiciousness | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Tearfulness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Investigations | | | |
| Activated Partial Thromboplastin Time Prolonged | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Activated Partial Thromboplastin Time Shortened | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Alanine Aminotransferase Increased | | | |
| subjects affected / exposed | 70 / 542 (12.92%) | 3 / 93 (3.23%) | 26 / 540 (4.81%) |
| occurrences (all) | 167 | 6 | 40 |
| Aspartate Aminotransferase Increased | | | |
| subjects affected / exposed | 63 / 542 (11.62%) | 4 / 93 (4.30%) | 25 / 540 (4.63%) |
| occurrences (all) | 114 | 4 | 35 |
| Blood Alkaline Phosphatase Increased | | | |

| | | | |
|---------------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 22 / 542 (4.06%) | 4 / 93 (4.30%) | 25 / 540 (4.63%) |
| occurrences (all) | 43 | 4 | 36 |
| Blood Amylase Increased | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 2 / 93 (2.15%) | 4 / 540 (0.74%) |
| occurrences (all) | 19 | 7 | 10 |
| Blood Bicarbonate Decreased | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 1 | 2 |
| Blood Calcium Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Blood Calcium Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood Chloride Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood Cortisol Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood Creatinine Increased | | | |
| subjects affected / exposed | 21 / 542 (3.87%) | 2 / 93 (2.15%) | 15 / 540 (2.78%) |
| occurrences (all) | 30 | 2 | 22 |
| Blood Folate Decreased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood Glucose Fluctuation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood Lactate Dehydrogenase Increased | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 6 / 540 (1.11%) |
| occurrences (all) | 7 | 0 | 7 |
| Blood Magnesium Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|----------------|-----------------|
| Blood Magnesium Increased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood Parathyroid Hormone Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood Phosphorus Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood Thyroid Stimulating Hormone Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood Urea Increased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Blood Uric Acid Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood Uric Acid Increased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 2 | 0 | 9 |
| Body Temperature Increased | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Brain Natriuretic Peptide Increased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Breath Sounds Abnormal | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 2 | 0 | 3 |
| Carbon Dioxide Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiac Murmur | | | |

| | | | |
|---|-----------------|----------------|-----------------|
| subjects affected / exposed | 8 / 542 (1.48%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 13 | 1 | 5 |
| Electrocardiogram Abnormal | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Ejection Fraction Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Electrocardiogram Pr Prolongation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Electrocardiogram QT Prolonged | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 11 | 0 | 4 |
| Electrocardiogram St Segment Depression | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Electrocardiogram QT Shortened | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Electrocardiogram T Wave Inversion | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Gamma-Glutamyltransferase Increased | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 0 | 6 |
| Glomerular Filtration Rate Decreased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematocrit Decreased | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 0 | 3 |
| Heart Rate Increased | | | |

| | | | |
|--|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Heart Rate Irregular | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Hepatic Enzyme Increased | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Inspiratory Capacity Decreased | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| International Normalised Ratio Decreased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| International Normalised Ratio Increased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intraocular Pressure Increased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 1 | 2 |
| Lasegue's Test Positive | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lipase Increased | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 6 |
| Liver Function Test Abnormal | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Liver Palpable Subcostal | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymph Node Palpable | | | |

| | | | |
|--------------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Lymphocyte Count Decreased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 0 | 3 |
| Lymphocyte Count Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Lymphocyte Percentage Decreased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 0 | 2 |
| Neutrophil Count Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Neutrophil Count Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Neutrophil Percentage Decreased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oxygen Saturation Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Platelet Count Decreased | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 10 | 1 | 1 |
| Platelet Count Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 1 | 1 |
| Prostatic Specific Antigen Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 0 | 0 | 3 |
| Protein Total Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Prothrombin Time Prolonged | | | |

| | | | |
|--------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Prothrombin Time Shortened | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| QRS Axis Abnormal | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Red Blood Cell Count Decreased | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 5 | 0 | 1 |
| Troponin I Increased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary Sediment Abnormal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary Sediment Present | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Urine Colour Abnormal | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Urine Output Increased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Vitamin B12 Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitamin D Decreased | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Waist Circumference Increased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 2 | 0 | 4 |
| Weight Decreased | | | |

| | | | |
|--|------------------|----------------|------------------|
| subjects affected / exposed | 42 / 542 (7.75%) | 6 / 93 (6.45%) | 27 / 540 (5.00%) |
| occurrences (all) | 66 | 6 | 38 |
| Weight Increased | | | |
| subjects affected / exposed | 29 / 542 (5.35%) | 2 / 93 (2.15%) | 40 / 540 (7.41%) |
| occurrences (all) | 43 | 2 | 48 |
| White Blood Cell Count Decreased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 6 | 0 | 3 |
| White Blood Cell Count Increased | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 2 | 3 |
| Injury, poisoning and procedural complications | | | |
| Accident at Home | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Accidental Overdose | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Alcohol Poisoning | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Animal Bite | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Arthropod Bite | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 8 | 0 | 3 |
| Arthropod Sting | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Back Injury | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 1 | 3 |
| Bone Fragmentation | | | |

| | | | |
|-----------------------------|-------------------|----------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cartilage Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cervical Vertebral Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chest Injury | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Clavicle Fracture | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Concussion | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Contrast Media Reaction | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences (all) | 4 | 1 | 7 |
| Contusion | | | |
| subjects affected / exposed | 81 / 542 (14.94%) | 6 / 93 (6.45%) | 49 / 540 (9.07%) |
| occurrences (all) | 116 | 10 | 72 |
| Corneal Abrasion | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Cystitis Radiation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Device Breakage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Excoriation | | | |
| subjects affected / exposed | 15 / 542 (2.77%) | 2 / 93 (2.15%) | 11 / 540 (2.04%) |
| occurrences (all) | 20 | 3 | 12 |
| Eye Injury | | | |

| | | | |
|-----------------------------|------------------|------------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Eye Penetration | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Face Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Facial Bones Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 47 / 542 (8.67%) | 12 / 93 (12.90%) | 20 / 540 (3.70%) |
| occurrences (all) | 60 | 13 | 29 |
| Fibula Fracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Foot Fracture | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 2 | 1 | 3 |
| Foreign Body in Eye | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis Radiation | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Hand Fracture | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Head Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Hip Fracture | | | |

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|-----------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Humerus Fracture | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Iliotibial Band Syndrome | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Incisional Hernia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Joint Dislocation | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Joint Injury | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 4 / 93 (4.30%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 4 | 4 |
| Joint Sprain | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 13 | 0 | 3 |
| Laceration | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Ligament Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ligament Rupture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Limb Injury | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 8 | 1 | 2 |
| Lumbar Vertebral Fracture | | | |

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|------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Meniscus Lesion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Mouth Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscle Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Muscle Rupture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscle Strain | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 2 / 93 (2.15%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 2 | 3 |
| Neck Injury | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Open Wound | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 0 | 0 | 3 |
| Patella Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pelvic Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Periorbital Haematoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Post Procedural Complication | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 3 |
| Post Procedural Discharge | | | |

| | | | |
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| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Post Procedural Discomfort | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Post Procedural Haematuria | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Post-Traumatic Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Procedural Pain | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 11 | 0 | 7 |
| Radiation Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Radiation Skin Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Radius Fracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rib Fracture | | | |
| subjects affected / exposed | 20 / 542 (3.69%) | 2 / 93 (2.15%) | 20 / 540 (3.70%) |
| occurrences (all) | 26 | 3 | 24 |
| Scapula Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Scratch | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Seroma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Skeletal Injury | | | |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 11 / 542 (2.03%) | 2 / 93 (2.15%) | 9 / 540 (1.67%) |
| occurrences (all) | 12 | 2 | 9 |
| Skin Injury | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin Laceration | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 6 / 93 (6.45%) | 15 / 540 (2.78%) |
| occurrences (all) | 24 | 10 | 21 |
| Soft Tissue Injury | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Spinal Compression Fracture | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 5 | 1 | 3 |
| Spinal Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Stent Occlusion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Stress Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Subdural Haematoma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Tendon Injury | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tendon Rupture | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Thoracic Vertebral Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 4 |
| Tibia Fracture | | | |

| | | | |
|--|------------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth Fracture | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 8 | 0 | 5 |
| Traumatic Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper Limb Fracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 1 | 1 |
| Wound | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 15 | 1 | 7 |
| Wound Complication | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Wrist Fracture | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Cryptorchism | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Phimosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cardiac disorders | | | |
| Angina Pectoris | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 0 / 93 (0.00%) | 9 / 540 (1.67%) |
| occurrences (all) | 12 | 0 | 11 |
| Angina Unstable | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Aortic Valve Disease | | | |

| | | | |
|-------------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aortic Valve Incompetence | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Arrhythmia | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 8 | 0 | 4 |
| Arrhythmia Supraventricular | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Arteriosclerosis Coronary Artery | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 24 / 542 (4.43%) | 3 / 93 (3.23%) | 22 / 540 (4.07%) |
| occurrences (all) | 30 | 6 | 27 |
| Atrial Flutter | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Atrial Tachycardia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Atrioventricular Block First Degree | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Bradycardia | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 0 | 4 |
| Bundle Branch Block Left | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bundle Branch Block Right | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Cardiac Disorder | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiac Failure | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Cardiac Failure Acute | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cardiac Failure Congestive | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 7 | 0 | 1 |
| Cardiac Flutter | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Cardiac Hypertrophy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cardiomegaly | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiovascular Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Chest Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Chest Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Conduction Disorder | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Extrasystoles | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 3 | 0 | 4 |
| Coronary Artery Disease | | | |

| | | | |
|------------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Hypertrophic Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Ischaemic Cardiomyopathy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Left Ventricular Dysfunction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Left Ventricular Hypertrophy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Mitral Valve Disease | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mitral Valve Incompetence | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myocardial Infarction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Myocardial Ischaemia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 6 / 540 (1.11%) |
| occurrences (all) | 2 | 0 | 7 |
| Palpitations | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 0 / 93 (0.00%) | 9 / 540 (1.67%) |
| occurrences (all) | 15 | 0 | 12 |
| Right Ventricular Failure | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sick Sinus Syndrome | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinus Arrhythmia | | | |

| | | | |
|------------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Sinus Bradycardia | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 5 | 0 | 3 |
| Sinus Tachycardia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 2 |
| Supraventricular Tachycardia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 1 | 1 |
| Tachyarrhythmia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Tachycardia | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 2 / 93 (2.15%) | 9 / 540 (1.67%) |
| occurrences (all) | 15 | 2 | 11 |
| Tricuspid Valve Incompetence | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ventricular Extrasystoles | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 0 | 3 |
| Wandering Pacemaker | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| Akathisia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 2 |
| Amnesia | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 1 | 3 |
| Aphasia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 4 |

| | | | |
|-----------------------------|-----------------|----------------|------------------|
| Aphonia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ataxia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Balance Disorder | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 5 | 1 | 13 |
| Bradykinesia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Brain Injury | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Burning Sensation | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 7 | 0 | 2 |
| Carotid Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Carpal Tunnel Syndrome | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cerebral Atrophy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cerebral Ischaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Cerebral Microangiopathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cerebrovascular Accident | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 0 | 0 | 3 |

| | | | |
|-------------------------------|-------------------|----------------|-------------------|
| Cluster Headache | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cognitive Disorder | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 1 | 4 |
| Convulsion | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 3 | 1 |
| Coordination Abnormal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dementia Alzheimer's Type | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Diabetic Autonomic Neuropathy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diabetic Neuropathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Disturbance in Attention | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 81 / 542 (14.94%) | 7 / 93 (7.53%) | 73 / 540 (13.52%) |
| occurrences (all) | 116 | 9 | 95 |
| Dizziness Postural | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 3 | 0 | 6 |
| Drooling | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dysaesthesia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| Dysarthria | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Dysgeusia | | | |
| subjects affected / exposed | 19 / 542 (3.51%) | 1 / 93 (1.08%) | 15 / 540 (2.78%) |
| occurrences (all) | 19 | 1 | 15 |
| Dyskinesia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysphasia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Encephalopathy | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epidural Lipomatosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epiduritis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Extrapyramidal Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Facial Neuralgia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Facial Paresis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Global Amnesia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-------------------|----------------|-------------------|
| Head Discomfort | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Headache | | | |
| subjects affected / exposed | 86 / 542 (15.87%) | 9 / 93 (9.68%) | 66 / 540 (12.22%) |
| occurrences (all) | 129 | 9 | 87 |
| Hydrocephalus | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperaesthesia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 1 | 0 | 3 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 18 / 542 (3.32%) | 0 / 93 (0.00%) | 12 / 540 (2.22%) |
| occurrences (all) | 22 | 0 | 15 |
| Hypoaesthesia Facial | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Hypogeusia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoglossal Nerve Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hyposmia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Iiird Nerve Paralysis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Loss of Consciousness | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Memory Impairment | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 9 / 540 (1.67%) |
| occurrences (all) | 7 | 1 | 9 |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| Migraine | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 2 |
| Migraine with Aura | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Monoplegia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Motor Dysfunction | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Myoclonus | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nerve Compression | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neuralgia | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 2 / 93 (2.15%) | 3 / 540 (0.56%) |
| occurrences (all) | 8 | 3 | 3 |
| Neuropathy Peripheral | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 7 / 93 (7.53%) | 6 / 540 (1.11%) |
| occurrences (all) | 23 | 7 | 6 |
| Nystagmus | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 25 / 542 (4.61%) | 1 / 93 (1.08%) | 17 / 540 (3.15%) |
| occurrences (all) | 33 | 2 | 18 |
| Parkinson's Disease | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Parosmia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|------------------------|---------------------|------------------------|
| Peripheral Motor Neuropathy subjects affected / exposed occurrences (all) | 6 / 542 (1.11%) 8 | 2 / 93 (2.15%) 2 | 1 / 540 (0.19%) 1 |
| Peripheral Sensory Neuropathy subjects affected / exposed occurrences (all) | 13 / 542 (2.40%) 24 | 0 / 93 (0.00%) 0 | 13 / 540 (2.41%) 17 |
| Peroneal Nerve Palsy subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Polyneuropathy subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 2 / 540 (0.37%) 2 |
| Poor Quality Sleep subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Post Herpetic Neuralgia subjects affected / exposed occurrences (all) | 2 / 542 (0.37%) 2 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Presyncope subjects affected / exposed occurrences (all) | 3 / 542 (0.55%) 3 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Radiculopathy subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 2 / 540 (0.37%) 2 |
| Reflexes Abnormal subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Restless Legs Syndrome subjects affected / exposed occurrences (all) | 3 / 542 (0.55%) 4 | 1 / 93 (1.08%) 2 | 1 / 540 (0.19%) 1 |
| Sciatica subjects affected / exposed occurrences (all) | 11 / 542 (2.03%) 13 | 1 / 93 (1.08%) 2 | 10 / 540 (1.85%) 14 |
| Sensory Disturbance subjects affected / exposed occurrences (all) | 2 / 542 (0.37%) 2 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |

| | | | |
|--|-------------------|------------------|------------------|
| Sinus Headache | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 8 | 0 | 1 |
| Somnolence | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences (all) | 4 | 1 | 5 |
| Speech Disorder Developmental | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Spinal Cord Compression | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 0 | 3 |
| Syncope | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 3 / 93 (3.23%) | 7 / 540 (1.30%) |
| occurrences (all) | 9 | 3 | 7 |
| Syncope Vasovagal | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 2 / 93 (2.15%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 2 | 2 |
| Transient Ischaemic Attack | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Tremor | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 3 / 93 (3.23%) | 6 / 540 (1.11%) |
| occurrences (all) | 11 | 3 | 6 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 59 / 542 (10.89%) | 12 / 93 (12.90%) | 53 / 540 (9.81%) |
| occurrences (all) | 112 | 17 | 84 |
| Anaemia of Malignant Disease | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Disseminated Intravascular Coagulation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhagic Anaemia | | | |

| | | | |
|---------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Haemorrhagic Diathesis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 9 | 0 | 7 |
| Lymphatic Obstruction | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 3 / 93 (3.23%) | 5 / 540 (0.93%) |
| occurrences (all) | 4 | 3 | 9 |
| Neutropenia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 0 | 5 |
| Normochromic Normocytic Anaemia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Pernicious Anaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Splenic Granuloma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Thrombocythaemia | | | |

| | | | |
|-----------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 26 | 0 | 13 |
| Ear and labyrinth disorders | | | |
| Cerumen Impaction | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Conductive Deafness | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Deafness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Ear Congestion | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Ear Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Ear Pain | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 11 | 0 | 1 |
| Eustachian Tube Dysfunction | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hearing Impaired | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Hyperacusis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoacusis | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 11 | 0 | 8 |

| | | | |
|-------------------------------|------------------|----------------|-----------------|
| Middle Ear Effusion | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tinnitus | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 8 / 540 (1.48%) |
| occurrences (all) | 4 | 0 | 8 |
| Tympanic Membrane Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tympanic Membrane Perforation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Vertigo | | | |
| subjects affected / exposed | 17 / 542 (3.14%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 22 | 1 | 5 |
| Eye disorders | | | |
| Abnormal Sensation in Eye | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Asthenopia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Astigmatism | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Blepharitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blindness Transient | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blindness Unilateral | | | |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Borderline Glaucoma | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cataract | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 4 / 93 (4.30%) | 12 / 540 (2.22%) |
| occurrences (all) | 18 | 5 | 14 |
| Conjunctival Haemorrhage | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Conjunctivitis | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 8 | 1 | 3 |
| Conjunctivitis Allergic | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Corneal Deposits | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diplopia | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 0 | 3 |
| Dry Eye | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 0 | 4 |
| Episcleritis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Erythema of Eyelid | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Exophthalmos | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye Discharge | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye Haemorrhage | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 1 | 2 |
| Eye Inflammation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Eye Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 3 / 93 (3.23%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 3 | 3 |
| Eye Swelling | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eyelid Irritation | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Eyelid Oedema | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eyelid Ptosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Glaucoma | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Keratoconjunctivitis Sicca | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Lacrimation Increased | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 0 | 3 |
| Macular Degeneration | | | |

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| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Mydriasis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Ocular Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Ocular Hyperaemia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 1 | 6 |
| Ocular Icterus | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Ocular Surface Disease | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Orbital Oedema | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Panophthalmitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Photopsia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Retinal Artery Occlusion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Retinal Detachment | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Retinal Vein Thrombosis | | | |

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| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vision Blurred | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 0 / 93 (0.00%) | 9 / 540 (1.67%) |
| occurrences (all) | 11 | 0 | 9 |
| Visual Acuity Reduced | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 1 | 0 | 3 |
| Visual Disturbance | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 4 | 0 | 4 |
| Vitreous Floaters | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Abdominal Discomfort | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 0 / 93 (0.00%) | 9 / 540 (1.67%) |
| occurrences (all) | 14 | 0 | 9 |
| Abdominal Distension | | | |
| subjects affected / exposed | 15 / 542 (2.77%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 15 | 1 | 12 |
| Abdominal Hernia | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Abdominal Mass | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal Pain | | | |
| subjects affected / exposed | 49 / 542 (9.04%) | 5 / 93 (5.38%) | 44 / 540 (8.15%) |
| occurrences (all) | 66 | 7 | 57 |
| Abdominal Pain Lower | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 16 | 0 | 8 |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 19 / 542 (3.51%) | 0 / 93 (0.00%) | 20 / 540 (3.70%) |
| occurrences (all) | 21 | 0 | 24 |

| | | | |
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| Abdominal Tenderness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Abdominal Wall Mass | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Anal Fistula | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Anal Haemorrhage | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Anal Pruritus | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Anorectal Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 2 | 0 | 3 |
| Ascites | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Barrett's Oesophagus | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bowel Movement Irregularity | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Breath Odour | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Change of Bowel Habit | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 1 | 0 | 3 |

| | | | |
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| Colitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 4 |
| Colitis Ischaemic | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Colonic Polyp | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 1 | 1 |
| Constipation | | | |
| subjects affected / exposed | 144 / 542 (26.57%) | 15 / 93 (16.13%) | 112 / 540 (20.74%) |
| occurrences (all) | 204 | 16 | 140 |
| Defaecation Urgency | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 7 | 0 | 1 |
| Dental Caries | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Dental Discomfort | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 135 / 542 (24.91%) | 13 / 93 (13.98%) | 98 / 540 (18.15%) |
| occurrences (all) | 203 | 16 | 142 |
| Diverticulum | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Diverticulum Intestinal | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Dry Mouth | | | |
| subjects affected / exposed | 20 / 542 (3.69%) | 2 / 93 (2.15%) | 16 / 540 (2.96%) |
| occurrences (all) | 26 | 2 | 16 |
| Duodenal Ulcer | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
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| Dyspepsia | | | |
| subjects affected / exposed | 62 / 542 (11.44%) | 1 / 93 (1.08%) | 28 / 540 (5.19%) |
| occurrences (all) | 78 | 1 | 29 |
| Dysphagia | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 2 / 93 (2.15%) | 11 / 540 (2.04%) |
| occurrences (all) | 5 | 2 | 14 |
| Enteritis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Enterovesical Fistula | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epigastric Discomfort | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 0 | 1 | 3 |
| Eructation | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 3 |
| Faecal Incontinence | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 2 |
| Faeces Discoloured | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Flatulence | | | |
| subjects affected / exposed | 23 / 542 (4.24%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 25 | 1 | 12 |
| Food Poisoning | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 1 | 2 |
| Frequent Bowel Movements | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastric Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|------------------------------------|------------------|----------------|------------------|
| Gastric Ulcer | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 2 / 93 (2.15%) | 5 / 540 (0.93%) |
| occurrences (all) | 8 | 2 | 5 |
| Gastritis Atrophic | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastritis Haemorrhagic | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal Angiodysplasia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Gastrointestinal Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal Motility Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 27 / 542 (4.98%) | 1 / 93 (1.08%) | 24 / 540 (4.44%) |
| occurrences (all) | 33 | 1 | 26 |
| Gingival Pain | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 1 | 1 |
| Gingivitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Glossodynia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Haematemesis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematochezia | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 2 / 93 (2.15%) | 7 / 540 (1.30%) |
| occurrences (all) | 9 | 2 | 7 |
| Haemorrhoidal Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Haemorrhoids | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 12 | 1 | 7 |
| Hiatus Hernia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 1 | 1 |
| Hypoaesthesia Oral | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Ileus | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Inflammatory Bowel Disease | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Intestinal Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intra-Abdominal Haematoma | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Lip Dry | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|--------------------|------------------|--------------------|
| Lip Swelling | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Lip Ulceration | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Loose Tooth | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Malocclusion | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Melaena | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Mesenteric Vein Thrombosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Mouth Ulceration | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 2 |
| Nausea | | | |
| subjects affected / exposed | 144 / 542 (26.57%) | 15 / 93 (16.13%) | 127 / 540 (23.52%) |
| occurrences (all) | 210 | 17 | 155 |
| Odynophagia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Oedema Mouth | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oesophageal Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oesophageal Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Oesophagitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Oral Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Oral Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral Pruritus | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oroantral Fistula | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Painful Defaecation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pancreatic Cyst | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pancreatic Insufficiency | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia Oral | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peptic Ulcer | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Periodontal Disease | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peritonitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
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| Pigmentation Buccal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 7 | 0 | 2 |
| Proctitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 1 | 1 |
| Rectal Haemorrhage | | | |
| subjects affected / exposed | 21 / 542 (3.87%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 24 | 1 | 12 |
| Rectal Polyp | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rectal Spasm | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reflux Oesophagitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Retching | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Salivary Hypersecretion | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Sensitivity of Teeth | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Small Intestinal Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stomach Discomfort | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 7 | 0 | 7 |

| | | | |
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| Stomatitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Tongue Black Hairy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Tongue Coated | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Tongue Ulceration | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Toothache | | | |
| subjects affected / exposed | 15 / 542 (2.77%) | 2 / 93 (2.15%) | 11 / 540 (2.04%) |
| occurrences (all) | 18 | 2 | 13 |
| Vomiting | | | |
| subjects affected / exposed | 86 / 542 (15.87%) | 12 / 93 (12.90%) | 61 / 540 (11.30%) |
| occurrences (all) | 115 | 14 | 76 |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Hepatomegaly | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 1 | 1 |
| Hepatotoxicity | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 1 / 93 (1.08%) | 8 / 540 (1.48%) |
| occurrences (all) | 26 | 1 | 13 |
| Jaundice | | | |

| | | | |
|--|------------------------|---------------------|-----------------------|
| subjects affected / exposed occurrences (all) | 3 / 542 (0.55%) 3 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Jaundice Cholestatic subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Actinic Keratosis | | | |
| subjects affected / exposed occurrences (all) | 8 / 542 (1.48%) 10 | 0 / 93 (0.00%) 0 | 4 / 540 (0.74%) 12 |
| Alopecia | | | |
| subjects affected / exposed occurrences (all) | 13 / 542 (2.40%) 14 | 2 / 93 (2.15%) 2 | 9 / 540 (1.67%) 9 |
| Angioedema | | | |
| subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Blister | | | |
| subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Blood Blister | | | |
| subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Campbell De Morgan Spots | | | |
| subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Cold Sweat | | | |
| subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Decubitus Ulcer | | | |
| subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 1 / 93 (1.08%) 1 | 1 / 540 (0.19%) 1 |
| Dermal Cyst | | | |
| subjects affected / exposed occurrences (all) | 6 / 542 (1.11%) 6 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |

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| Dermatitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 0 | 0 | 4 |
| Dermatitis Acneiform | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Dermatitis Contact | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Dry Skin | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 4 / 93 (4.30%) | 13 / 540 (2.41%) |
| occurrences (all) | 13 | 4 | 18 |
| Ecchymosis | | | |
| subjects affected / exposed | 25 / 542 (4.61%) | 1 / 93 (1.08%) | 19 / 540 (3.52%) |
| occurrences (all) | 32 | 1 | 26 |
| Eczema | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 0 | 3 |
| Erythema | | | |
| subjects affected / exposed | 16 / 542 (2.95%) | 2 / 93 (2.15%) | 9 / 540 (1.67%) |
| occurrences (all) | 17 | 3 | 9 |
| Facial Wasting | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhage Subcutaneous | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hair Growth Abnormal | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 20 / 542 (3.69%) | 0 / 93 (0.00%) | 21 / 540 (3.89%) |
| occurrences (all) | 26 | 0 | 27 |

| | | | |
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| Hyperkeratosis | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 5 | 2 | 1 |
| Hypertrichosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoaesthesia Facial | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Increased Tendency to Bruise | | | |
| subjects affected / exposed | 22 / 542 (4.06%) | 0 / 93 (0.00%) | 14 / 540 (2.59%) |
| occurrences (all) | 23 | 0 | 16 |
| Ingrowing Nail | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Keloid Scar | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Lentigo | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Lipohypertrophy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Livedo Reticularis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Nail Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Neurodermatitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 2 |
| Night Sweats | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 2 / 93 (2.15%) | 10 / 540 (1.85%) |
| occurrences (all) | 14 | 3 | 13 |

| | | | |
|---|-----------------|----------------|-----------------|
| Onychalgia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Onychoclasia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Onychomadesis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain of Skin | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Palmar-Plantar Erythrodysaesthesia Syndrome | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 2 |
| Periorbital Oedema | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 3 |
| Petechiae | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 0 | 4 |
| Photosensitivity Reaction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pigmentation Disorder | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pityriasis Rosea | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Precancerous Skin Lesion | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |

| | | | |
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| subjects affected / exposed | 17 / 542 (3.14%) | 0 / 93 (0.00%) | 10 / 540 (1.85%) |
| occurrences (all) | 19 | 0 | 11 |
| Pruritus Generalised | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Purpura | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 4 / 540 (0.74%) |
| occurrences (all) | 6 | 1 | 5 |
| Purpura Senile | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash | | | |
| subjects affected / exposed | 49 / 542 (9.04%) | 1 / 93 (1.08%) | 21 / 540 (3.89%) |
| occurrences (all) | 64 | 1 | 22 |
| Rash Erythematous | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Rash Follicular | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash Macular | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Rash Maculo-Papular | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Rash Papular | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Rash Pruritic | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Rash Vesicular | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rosacea | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Scab | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 7 | 0 | 1 |
| Scar | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Seborrhoeic Dermatitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin Atrophy | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 9 / 540 (1.67%) |
| occurrences (all) | 7 | 0 | 10 |
| Skin Discolouration | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 6 | 0 | 2 |
| Skin Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Skin Exfoliation | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Skin Fragility | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 2 / 93 (2.15%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 2 | 1 |
| Skin Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin Induration | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin Inflammation | | | |

| | | | |
|-----------------------------|------------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin Irritation | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin Lesion | | | |
| subjects affected / exposed | 15 / 542 (2.77%) | 2 / 93 (2.15%) | 5 / 540 (0.93%) |
| occurrences (all) | 18 | 2 | 6 |
| Skin Mass | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin Nodule | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Skin Striae | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin Toxicity | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin Ulcer | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 7 | 0 | 1 |
| Stasis Dermatitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Swelling Face | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Telangiectasia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Urticaria | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 3 | 0 | 4 |
| Renal and urinary disorders | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Anuria | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Azotaemia | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bladder Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bladder Disorder | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bladder Obstruction | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bladder Hypertrophy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bladder Pain | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bladder Stenosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bladder Spasm | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 1 | 1 |
| Calculus Bladder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Calculus Ureteric | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Calculus Urethral | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|-------------------|----------------|------------------|
| Chromaturia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Cystitis Noninfective | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Enuresis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 0 | 3 |
| Dysuria | | | |
| subjects affected / exposed | 21 / 542 (3.87%) | 1 / 93 (1.08%) | 21 / 540 (3.89%) |
| occurrences (all) | 26 | 1 | 26 |
| Glycosuria | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematuria | | | |
| subjects affected / exposed | 56 / 542 (10.33%) | 4 / 93 (4.30%) | 32 / 540 (5.93%) |
| occurrences (all) | 89 | 4 | 40 |
| Haemorrhage Urinary Tract | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 0 / 93 (0.00%) | 6 / 540 (1.11%) |
| occurrences (all) | 14 | 0 | 6 |
| Hydronephrosis | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 2 / 93 (2.15%) | 15 / 540 (2.78%) |
| occurrences (all) | 8 | 2 | 17 |
| Hydroureter | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Kidney Enlargement | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Leukocyturia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Micturition Urgency | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 1 / 93 (1.08%) | 12 / 540 (2.22%) |
| occurrences (all) | 12 | 1 | 12 |

| | | | |
|-----------------------------|-------------------|----------------|-------------------|
| Nephrolithiasis | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 6 | 0 | 3 |
| Nocturia | | | |
| subjects affected / exposed | 38 / 542 (7.01%) | 0 / 93 (0.00%) | 29 / 540 (5.37%) |
| occurrences (all) | 45 | 0 | 34 |
| Obstructive Uropathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Oliguria | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Pollakiuria | | | |
| subjects affected / exposed | 56 / 542 (10.33%) | 2 / 93 (2.15%) | 55 / 540 (10.19%) |
| occurrences (all) | 85 | 2 | 70 |
| Polyuria | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 1 | 3 |
| Proteinuria | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Pyelocaliectasis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal Colic | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Renal Failure | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 1 | 3 |
| Renal Failure Acute | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 4 | 0 | 5 |
| Renal Failure Chronic | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Renal Impairment | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 3 |
| Renal Mass | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Stress Urinary Incontinence | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 1 | 2 |
| Ureteric Obstruction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 2 | 0 | 3 |
| Ureteric Stenosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urethral Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urethral Obstruction | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Urethral Pain | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 6 | 1 | 5 |
| Urethral Stenosis | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Urge Incontinence | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary Bladder Haemorrhage | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|------------------------|---------------------|------------------------|
| Urinary Hesitation subjects affected / exposed occurrences (all) | 3 / 542 (0.55%) 3 | 1 / 93 (1.08%) 1 | 0 / 540 (0.00%) 0 |
| Urinary Incontinence subjects affected / exposed occurrences (all) | 37 / 542 (6.83%) 49 | 0 / 93 (0.00%) 0 | 25 / 540 (4.63%) 37 |
| Urinary Retention subjects affected / exposed occurrences (all) | 18 / 542 (3.32%) 24 | 1 / 93 (1.08%) 1 | 14 / 540 (2.59%) 16 |
| Urinary Tract Disorder subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Urinary Tract Inflammation subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Urinary Tract Obstruction subjects affected / exposed occurrences (all) | 6 / 542 (1.11%) 8 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Urinary Tract Pain subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Urine Abnormality subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Urine Flow Decreased subjects affected / exposed occurrences (all) | 8 / 542 (1.48%) 8 | 0 / 93 (0.00%) 0 | 8 / 540 (1.48%) 8 |
| Urine Odour Abnormal subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Urogenital Haemorrhage subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Endocrine disorders Adrenal Insufficiency | | | |

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| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Cushing's Syndrome | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cushingoid | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 1 / 93 (1.08%) | 12 / 540 (2.22%) |
| occurrences (all) | 8 | 1 | 13 |
| Feminisation Acquired | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Gynaecomastia | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 3 / 93 (3.23%) | 21 / 540 (3.89%) |
| occurrences (all) | 14 | 3 | 24 |
| Hyperparathyroidism | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperparathyroidism Primary | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Hypoparathyroidism | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoparathyroidism Secondary | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Pituitary-Dependent Cushing's Syndrome | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---------------------------|------------------------|---------------------------|
| Primary Hyperaldosteronism subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Steroid Withdrawal Syndrome subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Amyotrophy subjects affected / exposed occurrences (all) | 0 / 542 (0.00%) 0 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Arthralgia subjects affected / exposed occurrences (all) | 172 / 542 (31.73%) 302 | 19 / 93 (20.43%) 29 | 131 / 540 (24.26%) 195 |
| Arthritis subjects affected / exposed occurrences (all) | 4 / 542 (0.74%) 4 | 0 / 93 (0.00%) 0 | 2 / 540 (0.37%) 2 |
| Arthropathy subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Back Disorder subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Back Pain subjects affected / exposed occurrences (all) | 199 / 542 (36.72%) 359 | 26 / 93 (27.96%) 39 | 180 / 540 (33.33%) 311 |
| Bone Disorder subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 1 / 540 (0.19%) 1 |
| Bone Pain subjects affected / exposed occurrences (all) | 144 / 542 (26.57%) 229 | 14 / 93 (15.05%) 16 | 112 / 540 (20.74%) 159 |
| Bone Swelling subjects affected / exposed occurrences (all) | 1 / 542 (0.18%) 1 | 0 / 93 (0.00%) 0 | 0 / 540 (0.00%) 0 |
| Bunion | | | |

| | | | |
|---------------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bursitis | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 2 / 93 (2.15%) | 7 / 540 (1.30%) |
| occurrences (all) | 5 | 2 | 7 |
| Coccydynia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 5 / 540 (0.93%) |
| occurrences (all) | 2 | 0 | 5 |
| Dupuytren's Contracture | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Exostosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Flank Pain | | | |
| subjects affected / exposed | 27 / 542 (4.98%) | 1 / 93 (1.08%) | 16 / 540 (2.96%) |
| occurrences (all) | 30 | 1 | 21 |
| Foot Deformity | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Groin Pain | | | |
| subjects affected / exposed | 41 / 542 (7.56%) | 0 / 93 (0.00%) | 22 / 540 (4.07%) |
| occurrences (all) | 52 | 0 | 33 |
| Intervertebral Disc Compression | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Joint Range of Motion Decreased | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Joint Stiffness | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Joint Swelling | | | |

| | | | |
|-----------------------------|-------------------|----------------|--------------------|
| subjects affected / exposed | 7 / 542 (1.29%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 7 | 0 | 3 |
| Limb Discomfort | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 7 / 540 (1.30%) |
| occurrences (all) | 2 | 0 | 7 |
| Low Turnover Osteopathy | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lumbar Spinal Stenosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mobility Decreased | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 6 | 0 | 1 |
| Muscle Atrophy | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 0 | 2 |
| Muscle Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscle Mass | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle Spasms | | | |
| subjects affected / exposed | 78 / 542 (14.39%) | 2 / 93 (2.15%) | 111 / 540 (20.56%) |
| occurrences (all) | 107 | 2 | 173 |
| Muscle Twitching | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 1 | 0 | 3 |
| Muscular Weakness | | | |
| subjects affected / exposed | 35 / 542 (6.46%) | 5 / 93 (5.38%) | 42 / 540 (7.78%) |
| occurrences (all) | 55 | 6 | 52 |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 22 / 542 (4.06%) | 4 / 93 (4.30%) | 26 / 540 (4.81%) |
| occurrences (all) | 25 | 4 | 26 |
| Musculoskeletal Discomfort | | | |

| | | | |
|-----------------------------|-------------------|------------------|-------------------|
| subjects affected / exposed | 12 / 542 (2.21%) | 1 / 93 (1.08%) | 13 / 540 (2.41%) |
| occurrences (all) | 13 | 1 | 13 |
| Musculoskeletal Disorder | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal Pain | | | |
| subjects affected / exposed | 97 / 542 (17.90%) | 12 / 93 (12.90%) | 77 / 540 (14.26%) |
| occurrences (all) | 144 | 13 | 106 |
| Musculoskeletal Stiffness | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 6 / 540 (1.11%) |
| occurrences (all) | 11 | 0 | 6 |
| Myalgia | | | |
| subjects affected / exposed | 40 / 542 (7.38%) | 3 / 93 (3.23%) | 32 / 540 (5.93%) |
| occurrences (all) | 48 | 3 | 39 |
| Myopathy | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 2 | 2 | 8 |
| Myopathy Steroid | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 2 |
| Myosclerosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myositis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neck Mass | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Neck Pain | | | |
| subjects affected / exposed | 30 / 542 (5.54%) | 2 / 93 (2.15%) | 17 / 540 (3.15%) |
| occurrences (all) | 41 | 2 | 20 |
| Nodule on Extremity | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Osteitis | | | |

| | | | |
|-----------------------------|--------------------|------------------|-------------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Osteoarthritis | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 10 | 1 | 6 |
| Osteonecrosis | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 11 | 3 | 5 |
| Osteopenia | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 0 | 4 |
| Osteoporosis | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 3 / 93 (3.23%) | 7 / 540 (1.30%) |
| occurrences (all) | 13 | 4 | 7 |
| Osteoporotic Fracture | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain in Extremity | | | |
| subjects affected / exposed | 107 / 542 (19.74%) | 16 / 93 (17.20%) | 89 / 540 (16.48%) |
| occurrences (all) | 172 | 20 | 127 |
| Pain in Jaw | | | |
| subjects affected / exposed | 15 / 542 (2.77%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 23 | 1 | 7 |
| Pathological Fracture | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Periarthritis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Polyarthritis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Pubic Pain | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Rotator Cuff Syndrome | | | |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sensation of Heaviness | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Soft Tissue Disorder | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Spinal Column Stenosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Spinal Osteoarthritis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Synovial Cyst | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 0 | 2 |
| Tendon Pain | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Tendonitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 2 / 93 (2.15%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 2 | 2 |
| Torticollis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Trigger Finger | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper Extremity Mass | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vertebral Column Mass | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infections and infestations | | | |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| Abdominal Abscess | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal Wall Abscess | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abscess Jaw | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abscess Limb | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 1 | 1 |
| Abscess Oral | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Acute Sinusitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Arthritis Bacterial | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthritis Infective | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bacterial Sepsis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bacteriuria | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 34 / 542 (6.27%) | 0 / 93 (0.00%) | 14 / 540 (2.59%) |
| occurrences (all) | 39 | 0 | 16 |

| | | | |
|------------------------------------|------------------|----------------|-----------------|
| Bronchitis Bacterial | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchitis Viral | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bronchopulmonary Aspergillosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Campylobacter Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Campylobacter Intestinal Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Candidiasis | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 6 | 0 | 3 |
| Catheter Related Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Catheter Site Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Cellulitis | | | |
| subjects affected / exposed | 16 / 542 (2.95%) | 4 / 93 (4.30%) | 8 / 540 (1.48%) |
| occurrences (all) | 18 | 7 | 8 |
| Chest Wall Abscess | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Clostridial Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Clostridium Difficile Colitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|-------------------------------------|-----------------|----------------|-----------------|
| Cystitis | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 2 / 93 (2.15%) | 5 / 540 (0.93%) |
| occurrences (all) | 12 | 2 | 6 |
| Diverticulitis | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 9 | 0 | 4 |
| Ear Infection | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 10 | 0 | 0 |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Escherichia Urinary Tract Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| External Ear Cellulitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye Infection | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 5 | 1 | 2 |
| Eyelid Infection | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Febrile Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 3 |
| Folliculitis | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 5 | 0 | 4 |
| Fungal Infection | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 4 | 0 | 3 |
| Fungal Oesophagitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|-----------------|
| Fungal Skin Infection | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 0 | 3 |
| Furuncle | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 1 / 93 (1.08%) | 9 / 540 (1.67%) |
| occurrences (all) | 9 | 1 | 9 |
| Gastroenteritis Norovirus | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 3 / 93 (3.23%) | 3 / 540 (0.56%) |
| occurrences (all) | 9 | 4 | 3 |
| Gastrointestinal Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival Abscess | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gingival Infection | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 3 | 0 | 2 |
| Groin Abscess | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatitis C | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes Simplex | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Herpes Virus Infection | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

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|---|------------------|----------------|------------------|
| Herpes Zoster | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 2 / 93 (2.15%) | 8 / 540 (1.48%) |
| occurrences (all) | 11 | 2 | 9 |
| Hordeolum | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Infected Cyst | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infected Skin Ulcer | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Influenza | | | |
| subjects affected / exposed | 25 / 542 (4.61%) | 3 / 93 (3.23%) | 15 / 540 (2.78%) |
| occurrences (all) | 35 | 3 | 16 |
| Labyrinthitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Laryngitis | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 4 | 0 | 1 |
| Lobar Pneumonia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 3 | 0 | 1 |
| Localised Infection | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 5 | 1 | 5 |
| Lower Respiratory Tract Infection | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 5 / 93 (5.38%) | 13 / 540 (2.41%) |
| occurrences (all) | 17 | 8 | 16 |
| Lower Respiratory Tract Infection Viral | | | |

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|-----------------------------|-------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Lung Infection | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 3 | 0 | 3 |
| Nail Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 65 / 542 (11.99%) | 5 / 93 (5.38%) | 46 / 540 (8.52%) |
| occurrences (all) | 94 | 8 | 59 |
| Oesophageal Candidiasis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oesophageal Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 8 | 0 | 1 |
| Oral Candidiasis | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 2 / 93 (2.15%) | 10 / 540 (1.85%) |
| occurrences (all) | 13 | 3 | 10 |
| Oral Fungal Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Oral Herpes | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 13 | 1 | 5 |
| Oral Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis Externa | | | |

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|-------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis Media | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Paronychia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Parotitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pertussis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 5 | 0 | 4 |
| Pharyngitis Streptococcal | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 7 | 1 | 8 |
| Pneumonia Klebsiella | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Postoperative Wound Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Prostatic Abscess | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proteus Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyelonephritis | | | |

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| subjects affected / exposed | 1 / 542 (0.18%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rash Pustular | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 2 |
| Respiratory Tract Infection | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 6 | 1 | 5 |
| Rhinitis | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 2 | 1 | 3 |
| Rotavirus Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Salmonellosis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Septic Shock | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 29 / 542 (5.35%) | 3 / 93 (3.23%) | 5 / 540 (0.93%) |
| occurrences (all) | 43 | 3 | 5 |
| Skin Candida | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin Infection | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 8 | 1 | 1 |
| Soft Tissue Infection | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Staphylococcal Infection | | | |

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|-----------------------------------|-------------------|------------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Staphylococcal Sepsis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Streptococcal Infection | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tinea Cruris | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Tinea Pedis | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 5 | 0 | 1 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth Abscess | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 7 / 540 (1.30%) |
| occurrences (all) | 4 | 1 | 8 |
| Tooth Infection | | | |
| subjects affected / exposed | 13 / 542 (2.40%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 15 | 1 | 4 |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 74 / 542 (13.65%) | 4 / 93 (4.30%) | 43 / 540 (7.96%) |
| occurrences (all) | 108 | 5 | 58 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 49 / 542 (9.04%) | 11 / 93 (11.83%) | 40 / 540 (7.41%) |
| occurrences (all) | 73 | 21 | 61 |
| Urinary Tract Infection Bacterial | | | |

| | | | |
|---|-------------------|------------------|------------------|
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Urinary Tract Infection Pseudomonal | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 1 / 93 (1.08%) | 0 / 540 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urosepsis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 2 |
| Viral Infection | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 2 | 0 | 4 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 1 / 93 (1.08%) | 1 / 540 (0.19%) |
| occurrences (all) | 8 | 1 | 1 |
| Wound Infection | | | |
| subjects affected / exposed | 4 / 542 (0.74%) | 1 / 93 (1.08%) | 2 / 540 (0.37%) |
| occurrences (all) | 4 | 1 | 2 |
| Metabolism and nutrition disorders | | | |
| Anorexia | | | |
| subjects affected / exposed | 56 / 542 (10.33%) | 10 / 93 (10.75%) | 40 / 540 (7.41%) |
| occurrences (all) | 75 | 11 | 46 |
| Central Obesity | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Decreased Appetite | | | |
| subjects affected / exposed | 28 / 542 (5.17%) | 0 / 93 (0.00%) | 30 / 540 (5.56%) |
| occurrences (all) | 31 | 0 | 31 |
| Dehydration | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 4 / 93 (4.30%) | 18 / 540 (3.33%) |
| occurrences (all) | 17 | 5 | 20 |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 0 / 93 (0.00%) | 8 / 540 (1.48%) |
| occurrences (all) | 12 | 0 | 8 |
| Diabetes Mellitus Inadequate Control | | | |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Dyslipidaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Failure to Thrive | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 0 | 0 | 3 |
| Fluid Retention | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 0 / 93 (0.00%) | 3 / 540 (0.56%) |
| occurrences (all) | 6 | 0 | 3 |
| Glucose Tolerance Impaired | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Gout | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 1 |
| Hyperalbuminaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 2 / 540 (0.37%) |
| occurrences (all) | 1 | 0 | 2 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 6 / 540 (1.11%) |
| occurrences (all) | 13 | 0 | 6 |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 20 / 542 (3.69%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 21 | 1 | 11 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 52 / 542 (9.59%) | 6 / 93 (6.45%) | 41 / 540 (7.59%) |
| occurrences (all) | 93 | 7 | 74 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 12 / 542 (2.21%) | 1 / 93 (1.08%) | 11 / 540 (2.04%) |
| occurrences (all) | 19 | 1 | 14 |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 1 | 0 | 1 |
| Hypermagnesaemia | | | |

| | | | |
|-----------------------------|-------------------|----------------|-------------------|
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 14 | 1 | 8 |
| Hypernatraemia | | | |
| subjects affected / exposed | 9 / 542 (1.66%) | 0 / 93 (0.00%) | 10 / 540 (1.85%) |
| occurrences (all) | 20 | 0 | 14 |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 2 | 0 | 2 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 2 / 93 (2.15%) | 5 / 540 (0.93%) |
| occurrences (all) | 8 | 3 | 6 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 4 | 1 | 6 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 5 / 542 (0.92%) | 3 / 93 (3.23%) | 5 / 540 (0.93%) |
| occurrences (all) | 9 | 4 | 11 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 8 / 542 (1.48%) | 2 / 93 (2.15%) | 2 / 540 (0.37%) |
| occurrences (all) | 12 | 2 | 5 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 4 / 540 (0.74%) |
| occurrences (all) | 2 | 0 | 5 |
| Hypokalaemia | | | |
| subjects affected / exposed | 99 / 542 (18.27%) | 9 / 93 (9.68%) | 68 / 540 (12.59%) |
| occurrences (all) | 176 | 13 | 107 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 7 / 542 (1.29%) | 2 / 93 (2.15%) | 6 / 540 (1.11%) |
| occurrences (all) | 8 | 2 | 6 |
| Hyponatraemia | | | |
| subjects affected / exposed | 14 / 542 (2.58%) | 5 / 93 (5.38%) | 15 / 540 (2.78%) |
| occurrences (all) | 31 | 7 | 19 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 11 / 542 (2.03%) | 2 / 93 (2.15%) | 8 / 540 (1.48%) |
| occurrences (all) | 20 | 2 | 19 |
| Hypovolaemia | | | |

| | | | |
|-----------------------------|------------------|----------------|------------------|
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Increased Appetite | | | |
| subjects affected / exposed | 10 / 542 (1.85%) | 0 / 93 (0.00%) | 11 / 540 (2.04%) |
| occurrences (all) | 11 | 0 | 11 |
| Malnutrition | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Metabolic Acidosis | | | |
| subjects affected / exposed | 0 / 542 (0.00%) | 0 / 93 (0.00%) | 1 / 540 (0.19%) |
| occurrences (all) | 0 | 0 | 1 |
| Polydipsia | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tetany | | | |
| subjects affected / exposed | 1 / 542 (0.18%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Type 1 Diabetes Mellitus | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 0 / 93 (0.00%) | 0 / 540 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Type 2 Diabetes Mellitus | | | |
| subjects affected / exposed | 3 / 542 (0.55%) | 1 / 93 (1.08%) | 6 / 540 (1.11%) |
| occurrences (all) | 3 | 1 | 6 |
| Vitamin B12 Deficiency | | | |
| subjects affected / exposed | 2 / 542 (0.37%) | 1 / 93 (1.08%) | 3 / 540 (0.56%) |
| occurrences (all) | 2 | 1 | 3 |
| Vitamin D Deficiency | | | |
| subjects affected / exposed | 6 / 542 (1.11%) | 1 / 93 (1.08%) | 5 / 540 (0.93%) |
| occurrences (all) | 6 | 1 | 5 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|--|
| 14 April 2010 | Expansion of genetic analyses to include biomarkers other than TMPRSS2-ERG |
| 07 June 2011 | Inclusion of an additional interim analysis of the Overall Survival (OS) co-primary endpoint, adjustment of the timing of the interim analyses for OS and addition of a strategy to adjust for a potential cross-over effect |
| 02 April 2012 | Updated the eligibility criteria and modified the schedule of events for subjects who will cross over from placebo to abiraterone acetate after the study drug assignments were unblinded, provided information on the IDMC recommendation to unblind the treatment assignments. |
| 09 July 2012 | The main reason of this amendment was to to allow subjects who had formerly received placebo treatment but had discontinued from the protocol and who met the eligibility criteria under Amendment 4, to also receive treatment with abiraterone acetate. |

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.

These results are up to clinical cutoff (CCO) date (that is, 31 March 2014).

Notes: