# Clinical trial results:
# A Randomized, Open-Label, Comparative Evaluation of Conversion From Calcineurin Inhibitors to Sirolimus Versus Continued Use of Calcineurin Inhibitors in Renal Allograft Recipients

## Summary

| | |
|---|---|
| EudraCT number | 2006-005687-44 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 21 May 2008 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 30 May 2016 |
| First version publication date | 31 July 2015 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | 0468H1-316 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00038948 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Alias: B1741186 |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Clinical Trials.gov Call Center, Pfizer Inc, 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 12 December 2008 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 21 May 2008 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To determine the effect of conversion from calcineurin inhibitor (CNI)- to sirolimus (SRL)-based therapy on renal function 52 weeks after randomization, as indicated by the change from baseline calculated glomerular filtration rate (GFR) (Nankivell method), and to demonstrate:
a)superiority of the SRL conversion versus CNI continuation regimens in subjects with baseline Nankivell GFRs greater than (>) 40 milliliter per minute (mL/min). OR
b)noninferiority of the SRL conversion versus CNI continuation regimens in subjects with baseline Nankivell GFRs of 20 to 40 mL/min, and to establish superiority in this group if the results are consistent with this conclusion.
To assess equivalence 52 weeks after randomization between treatment groups in the composite endpoint of the incidence of the first occurrence of biopsy-confirmed acute rejection, graft loss, or death.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 05 February 2002 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 1 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Singapore: 7 |
| Country: Number of subjects enrolled | France: 25 |
| Country: Number of subjects enrolled | South Africa: 31 |
| Country: Number of subjects enrolled | Denmark: 3 |
| Country: Number of subjects enrolled | Czech Republic: 33 |
| Country: Number of subjects enrolled | Portugal: 21 |
| Country: Number of subjects enrolled | Mexico: 126 |
| Country: Number of subjects enrolled | Italy: 46 |
| Country: Number of subjects enrolled | Argentina: 68 |
| Country: Number of subjects enrolled | Sweden: 2 |
| Country: Number of subjects enrolled | Poland: 37 |
| Country: Number of subjects enrolled | Brazil: 80 |

| | |
|---|---|
| Country: Number of subjects enrolled | Chile: 9 |
| Country: Number of subjects enrolled | Germany: 10 |
| Country: Number of subjects enrolled | Saudi Arabia: 2 |
| Country: Number of subjects enrolled | Spain: 59 |
| Country: Number of subjects enrolled | Austria: 13 |
| Country: Number of subjects enrolled | Belgium: 7 |
| Country: Number of subjects enrolled | Australia: 38 |
| Country: Number of subjects enrolled | Canada: 37 |
| Country: Number of subjects enrolled | United States: 176 |
| Worldwide total number of subjects | 830 |
| EEA total number of subjects | 256 |

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) | 38 |
| Adults (18-64 years) | 751 |
| From 65 to 84 years | 41 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Subjects were recruited worldwide from January 2002 to September 2003.

### Pre-assignment

Screening details:

Subjects were screened for two weeks.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | SRL Conversion in Stable Renal Transplant Recipients |

Arm description:

Conversion from calcineurin inhibitor immunosuppression therapy to Sirolimus-based immunosuppression therapy.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Sirolimus |
| Investigational medicinal product code | |
| Other name | Rapamune |
| Pharmaceutical forms | Oral solution, Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

SRL was concentration-controlled and adjusted to achieve a whole blood trough level in the range of 8 to 20 nanogram per milliliter (ng/mL). SRL was administered for the entire 208-weeks treatment period.

| | |
|---|---|
| **Arm title** | CNI Continuation in Stable Renal Transplant Recipients |

Arm description:

Continued calcineurin inhibitor immunosuppression therapy. Subjects in this arm will receive either CsA or TAC.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Cyclosporine (cyclosporin A):CsA |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral solution, Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

CsA trough concentrations was monitored at designated intervals and the CsA dose adjusted to maintain the following trough concentration ranges: CsA 50-250 ng/mL. Subjects continue to receive CsA for the entire 208-week treatment period. The investigators supplied CNIs in the appropriate formulation available in their region.

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

Dosage and administration details:

Tacrolimus (TAC) trough concentrations was monitored at designated intervals and the TAC dose adjusted to maintain the following trough concentration ranges: TAC 4-10 ng/mL. Subjects continue to

receive tacrolimus for the entire 208-week treatment period. The investigators supplied TAC in the appropriate formulation available in their region.

| **Number of subjects in period 1** | SRL Conversion in Stable Renal Transplant Recipients | CNI Continuation in Stable Renal Transplant Recipients |
|---|---|---|
| Started | 555 | 275 |
| Completed | 441 | 222 |
| Not completed | 114 | 53 |
| Randomized, but not treated | 4 | 2 |
| No longer willing to participate in study | 31 | 19 |
| Adverse event | 19 | 6 |
| Lost to follow-up | 35 | 18 |
| Subject Died | 25 | 8 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | SRL Conversion in Stable Renal Transplant Recipients |
| Reporting group description: | |
| Conversion from calcineurin inhibitor immunosuppression therapy to Sirolimus-based immunosuppression therapy. | |
| Reporting group title | CNI Continuation in Stable Renal Transplant Recipients |
| Reporting group description: | |
| Continued calcineurin inhibitor immunosuppression therapy. Subjects in this arm will receive either CsA or TAC. | |

| Reporting group values | SRL Conversion in Stable Renal Transplant Recipients | CNI Continuation in Stable Renal Transplant Recipients | Total |
|---|---|---|---|
| Number of subjects | 555 | 275 | 830 |
| Age categorical<br>Units: Subjects | | | |
| Age continuous<br>Units: years | | | |
| median | 45 | 43.5 | |
| full range (min-max) | 13.2 to 75.1 | 12.8 to 74 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 170 | 81 | 251 |
| Male | 385 | 194 | 579 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | SRL Conversion in Stable Renal Transplant Recipients |
| Reporting group description: | |
| Conversion from calcineurin inhibitor immunosuppression therapy to Sirolimus-based immunosuppression therapy. | |
| Reporting group title | CNI Continuation in Stable Renal Transplant Recipients |
| Reporting group description: | |
| Continued calcineurin inhibitor immunosuppression therapy. Subjects in this arm will receive either CsA or TAC. | |
| Subject analysis set title | SRL Conversion Strata 20.0-40.0 milliliter/minute (mL/Min) |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| Conversion from calcineurin inhibitor immunosuppression therapy to Sirolimus-based immunosuppression therapy in stable renal transplant recipients. | |
| Subject analysis set title | CNI Continuation Strata 20.0-40.0 mL/Min |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| Continued calcineurin inhibitor immunosuppression therapy in renal transplant recipients. | |
| Subject analysis set title | SRL Conversion Strata >40.0 mL/Min |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| Conversion from calcineurin inhibitor immunosuppression therapy to Sirolimus-based immunosuppression therapy in renal transplant recipients. | |
| Subject analysis set title | CNI Continuation Strata >40.0 mL/Min |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| Continued calcineurin inhibitor immunosuppression therapy in renal transplant recipients. | |

### Primary: Nankivell Glomerular Filtration Rate (GFR) at Week 52

| | |
|---|---|
| End point title | Nankivell Glomerular Filtration Rate (GFR) at Week 52 |
| End point description: | |
| Nankivell GFR: subjects with baseline GFR of 20.0 to 40.0 mL/min and subjects with baseline GFR of greater than 40.0 mL/min. GFR is an index of kidney function. A higher value means better kidney function. Subjects were stratified by GFR at baseline. GFR 20-40 mL/min and GFR >40 mL/min. Arithmetic mean as from ANCOVA model adjusted for center and baseline. | |
| End point type | Primary |
| End point timeframe: | |
| 52 weeks | |

| End point values | SRL Conversion Strata 20.0-40.0 milliliter/minute (mL/Min) | CNI Continuation Strata 20.0-40.0 mL/Min | SRL Conversion Strata >40.0 mL/Min | CNI Continuation Strata >40.0 mL/Min |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 58 | 29 | 496 | 245 |
| Units: mL/min | | | | |
| arithmetic mean (standard error) | 24.56 (± 2.42) | 27.24 (± 3.71) | 59.04 (± 0.89) | 57.73 (± 1.1) |

## Statistical analyses

| **Statistical analysis title** | Baseline GFR of 20.0 to 40.0 mL/min |
|---|---|
| Statistical analysis description: | |
| Data was adjusted for baseline and center. | |
| Comparison groups | SRL Conversion Strata 20.0-40.0 milliliter/minute (mL/Min) v CNI Continuation Strata 20.0-40.0 mL/Min |
| Number of subjects included in analysis | 87 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.575 [1] |
| Method | ANCOVA |
| Parameter estimate | Weighted difference |
| Point estimate | -2.68 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.27 |
| upper limit | 6.91 |

Notes:

[1] - Analysis of covariance P-value for testing the equality of mean GFR at week 52 between treatments.

| **Statistical analysis title** | Baseline GFR of >40.0 mL/min |
|---|---|
| Statistical analysis description: | |
| Data was adjusted for baseline and center. | |
| Comparison groups | CNI Continuation Strata >40.0 mL/Min v SRL Conversion Strata >40.0 mL/Min |
| Number of subjects included in analysis | 741 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.278 [2] |
| Method | ANCOVA |
| Parameter estimate | Weighted difference |
| Point estimate | 1.31 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.06 |
| upper limit | 3.69 |

Notes:

[2] - Analysis of covariance P-value for testing the equality of mean GFR at week 52 between treatments.

## Primary: First Occurrence of Biopsy-confirmed Acute Rejection, Graft Loss, or Death

| End point title | First Occurrence of Biopsy-confirmed Acute Rejection, Graft Loss, or Death |
|---|---|

End point description:

Number of subjects who experienced for the first time either biopsy-confirmed acute rejection, graft loss, or death by weeks 52 and 104. Assessed by individual endpoint and as composite endpoint (all combined). Subjects were stratified by GFR at baseline. GFR 20-40 mL/min and GFR >40 mL/min. The outcome measure was primary safety endpoint.

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

End point timeframe:

52 and 104 weeks

| **End point values** | SRL Conversion Strata 20.0-40.0 milliliter/minute (mL/Min) | CNI Continuation Strata 20.0-40.0 mL/Min | SRL Conversion Strata >40.0 mL/Min | CNI Continuation Strata >40.0 mL/Min |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 58 | 29 | 497 | 246 |
| Units: subjects | | | | |
| 52 weeks - Acute rejection | 4 | 0 | 8 | 3 |
| 52 weeks - Graft loss | 7 | 3 | 3 | 3 |
| 52 weeks - Death | 3 | 0 | 6 | 1 |
| 52 weeks - Missing | 0 | 0 | 5 | 1 |
| 104 weeks - Acute rejection | 5 | 1 | 27 | 9 |
| 104 weeks - Graft loss | 12 | 9 | 12 | 8 |
| 104 weeks - Death | 7 | 0 | 13 | 3 |
| 104 weeks - Missing | 0 | 2 | 13 | 8 |

## Statistical analyses

| **Statistical analysis title** | 52 Weeks Statistical Analysis Across Strata |
|---|---|
| Comparison groups | SRL Conversion Strata 20.0-40.0 milliliter/minute (mL/Min) v CNI Continuation Strata 20.0-40.0 mL/Min v SRL Conversion Strata >40.0 mL/Min v CNI Continuation Strata >40.0 mL/Min |
| Number of subjects included in analysis | 830 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | = 0.135 [3] |
| Method | Cochran-Mantel-Haenszel |

Notes:

[3] - P-value for testing the equality of rates between treatments across strata at 52 weeks.

| **Statistical analysis title** | 104 Weeks Statistical Analysis Across Strata |
|---|---|
| Comparison groups | SRL Conversion Strata 20.0-40.0 milliliter/minute (mL/Min) v CNI Continuation Strata 20.0-40.0 mL/Min v SRL Conversion Strata >40.0 mL/Min v CNI Continuation Strata >40.0 mL/Min |

| | |
|---|---|
| Number of subjects included in analysis | 830 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| P-value | = 0.559 [4] |
| Method | Cochran-Mantel-Haenszel |

Notes:

[4] - P-value for testing the equality of rates between treatments across strata at 104 weeks.

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline up to 212 weeks

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events.An event may be categorized as serious in 1 subject and as non-serious in another, or 1 subject may have experienced both serious, non-serious event during study. EU BR specific AE tables were generated separately as per EU format using latest coding.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 17.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | SRL Conversion in Stable Renal Transplant Recipients |

Reporting group description:

Conversion from calcineurin inhibitor immunosuppression therapy to Sirolimus-based immunosuppression therapy.

| | |
|---|---|
| Reporting group title | CNI Continuation in Stable Renal Transplant Recipients |

Reporting group description:

Continued calcineurin inhibitor immunosuppression therapy.

| Serious adverse events | SRL Conversion in Stable Renal Transplant Recipients | CNI Continuation in Stable Renal Transplant Recipients | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 364 / 551 (66.06%) | 152 / 273 (55.68%) | |
| number of deaths (all causes) | 33 | 11 | |
| number of deaths resulting from adverse events | 11 | 4 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma of the cervix | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenoma benign | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anogenital warts | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bowen's disease | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 4 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 9 / 551 (1.63%) | 12 / 273 (4.40%) | |
| occurrences causally related to treatment / all | 7 / 13 | 20 / 24 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Basosquamous carcinoma | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Astrocytoma malignant | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast cancer | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic myeloid leukaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clear cell renal cell carcinoma | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cancer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal stromal tumour | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glioblastoma multiforme | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric cancer | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung adenocarcinoma | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laryngeal squamous cell carcinoma | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lip squamous cell carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Keratoacanthoma | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoproliferative disorder | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 1 / 2 | 7 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Papilloma | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuroendocrine carcinoma of the skin | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian adenoma | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neoplasm skin | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post transplant lymphoproliferative disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal cancer | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostate cancer | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 5 / 9 | 6 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cell carcinoma | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin cancer | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 2 / 2 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seminoma | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma | | | |
| subjects affected / exposed | 8 / 551 (1.45%) | 13 / 273 (4.76%) | |
| occurrences causally related to treatment / all | 9 / 15 | 20 / 48 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of head and neck | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of the tongue | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 5 / 273 (1.83%) | |
| occurrences causally related to treatment / all | 2 / 4 | 3 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma of colon | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Breast cancer metastatic | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Vascular disorders | | | |
| Aortic disorder | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic aneurysm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angiopathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aneurysm | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accelerated hypertension | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 14 / 551 (2.54%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 7 / 16 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial thrombosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic stenosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic vascular disorder | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive emergency | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive crisis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 9 / 551 (1.63%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 0 / 9 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Extremity necrosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Embolism | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphocele | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic venous thrombosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral arterial occlusive disease | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iliac vein occlusion | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent claudication | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral artery stenosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral venous disease | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral ischaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 551 (0.73%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 4 / 7 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral vascular disorder | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral embolism | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vena cava thrombosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phlebitis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Shock haemorrhagic | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 1 / 2 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombosis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Incisional hernia repair | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cancer surgery | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Unintended pregnancy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chills | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 551 (1.09%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest discomfort | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain | | | |
| subjects affected / exposed | 9 / 551 (1.63%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 2 / 10 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device malfunction | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device dislocation | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic cyst | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised oedema | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granuloma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Face oedema | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug intolerance | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device occlusion | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperpyrexia | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernia | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Impaired healing | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 3 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incarcerated hernia | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza like illness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Serositis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 48 / 551 (8.71%) | 15 / 273 (5.49%) | |
| occurrences causally related to treatment / all | 31 / 73 | 1 / 16 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mass | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 8 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multi-organ failure | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 3 | 0 / 0 | |
| Oedema peripheral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 7 / 551 (1.27%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sudden death | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Immune system disorders | | | |
| Transplant rejection | | | |
| subjects affected / exposed | 16 / 551 (2.90%) | 7 / 273 (2.56%) | |
| occurrences causally related to treatment / all | 4 / 17 | 4 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Kidney transplant rejection | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amyloidosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|---|---|
| Endometrial hyperplasia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metrorrhagia | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 2 / 4 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Menorrhagia | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic ovarian cyst | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian mass | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prostatitis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cough | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial lung disease | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 8 / 8 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemoptysis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infiltration | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleuritic pain | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 5 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillar haemorrhage | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillar hypertrophy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord disorder | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 17 / 551 (3.09%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 5 / 24 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Lung disorder | | | |
| subjects affected / exposed | 8 / 551 (1.45%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 2 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Pleural effusion | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 6 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory acidosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 1 | |
| Psychiatric disorders | | | |
| Agitation | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug abuse | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Confusional state | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide attempt | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood glucose abnormal | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood parathyroid hormone | | | |

| | | | |
|---|---|---|---|
| increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood pressure increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biopsy site unspecified abnormal | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood urea increased | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| C-reactive protein increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbohydrate antigen 125 increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug level increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium test positive | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coagulation time prolonged | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus test positive | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbon dioxide decreased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric occult blood positive | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerular filtration rate decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematology test abnormal | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver function test abnormal | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transaminases abnormal | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcus test | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood creatinine increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 38 / 551 (6.90%) | 15 / 273 (5.49%) | |
| occurrences causally related to treatment / all | 16 / 53 | 5 / 20 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Accident | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accidental overdose | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula site complication | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complications of transplant surgery | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic allograft nephropathy | | | |
| subjects affected / exposed | 13 / 551 (2.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 3 / 16 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula thrombosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula site haemorrhage | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|---|---|
| Arteriovenous fistula aneurysm | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle fracture | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot fracture | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft thrombosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur fracture | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complications of transplanted kidney | | | |
| subjects affected / exposed | 18 / 551 (3.27%) | 8 / 273 (2.93%) | |
| occurrences causally related to treatment / all | 9 / 29 | 2 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft complication | | | |

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|---|---|---|---|
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft loss | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb traumatic amputation | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site complication | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incisional hernia | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonitis chemical | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overdose | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medication error | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower limb fracture | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural complication | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haematoma | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal haematoma | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal transplant failure | | | |
| subjects affected / exposed | 21 / 551 (3.81%) | 20 / 273 (7.33%) | |
| occurrences causally related to treatment / all | 6 / 27 | 4 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seroma | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural complication | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound complication | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subdural haemorrhage | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon rupture | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to various agents | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic haemothorax | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper limb fracture | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular procedure complication | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular pseudoaneurysm | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound complication | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound dehiscence | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound necrosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound secretion | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Congenital cystic kidney disease | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic cardiomyopathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina unstable | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Atrial fibrillation | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial flutter | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial thrombosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac tamponade | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac failure acute | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericardial effusion | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 8 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mitral valve incompetence | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyanosis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary artery disease | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis constrictive | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Right ventricular failure | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arrhythmia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute myocardial infarction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardiac arrest | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 1 | |
| Cardiac failure | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Cardiac failure congestive | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 13 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cor pulmonale | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Nervous system disorders | | | |
| Anosmia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arachnoid cyst | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain mass | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hemiparesis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic stroke | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IVth nerve paralysis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive encephalopathy | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lethargy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningism | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neurological decompensation | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve compression | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uraemic encephalopathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post herpetic neuralgia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Trigeminal neuralgia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| VIIth nerve paralysis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vocal cord paralysis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage intracranial | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Subarachnoid haemorrhage | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Haemorrhagic stroke | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 27 / 551 (4.90%) | 5 / 273 (1.83%) | |
| occurrences causally related to treatment / all | 15 / 34 | 2 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemolytic uraemic syndrome | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancytopenia | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pseudolymphoma | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Microangiopathic haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukopenia | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 4 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombotic microangiopathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Cataract | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal hernia | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain | | | |
| subjects affected / exposed | 20 / 551 (3.63%) | 5 / 273 (1.83%) | |
| occurrences causally related to treatment / all | 8 / 25 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fissure | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aphthous stomatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic gastritis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute abdomen | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 36 / 551 (6.53%) | 6 / 273 (2.20%) | |
| occurrences causally related to treatment / all | 21 / 45 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticular perforation | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenitis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecal incontinence | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faeces discoloured | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flatulence | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric polyps | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal angiodysplasia haemorrhagic | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorder | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal necrosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernial eventration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal perforation | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal hernia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal ulcer | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical ileus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mouth ulceration | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea | | | |
| subjects affected / exposed | 9 / 551 (1.63%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 1 / 10 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophageal ulcer | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Melaena | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis haemorrhagic | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic cyst | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic necrosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oesophagitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic ulcer perforation | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 11 / 551 (2.00%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 2 / 13 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctitis ulcerative | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Oesophageal rupture | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| **Hepatobiliary disorders** | | | |
| Bile duct stone | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis acute | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-alcoholic steatohepatitis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatosplenomegaly | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular injury | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis chronic active | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis acute | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic pain | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cirrhosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hepatic failure | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| **Skin and subcutaneous tissue disorders** | | | |
| Acne | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angioedema | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decubitus ulcer | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis exfoliative | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ulcer | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exfoliative rash | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granuloma skin | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 4 / 6 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin disorder | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin exfoliation | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin lesion | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 2 / 2 | 1 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin necrosis | | | |

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|---|---|---|---|
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin ulcer | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 5 / 10 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxic skin eruption | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Renal and urinary disorders** | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 17 / 551 (3.09%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 1 / 23 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anuria | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Azotaemia | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 1 / 10 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic kidney disease | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 2 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysuria | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Focal segmental glomerulosclerosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 551 (0.91%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 6 / 9 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis membranous | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis rapidly progressive | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| IgA nephropathy | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydronephrosis | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Micturition urgency | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephropathy | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 9 / 551 (1.63%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 12 / 16 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oliguria | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pollakiuria | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal artery stenosis | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proteinuria | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 4 / 7 | 2 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal cyst haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal impairment | | | |
| subjects affected / exposed | 14 / 551 (2.54%) | 7 / 273 (2.56%) | |
| occurrences causally related to treatment / all | 6 / 20 | 3 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal failure | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal disorder | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal infarct | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal mass | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal tubular acidosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal tubular necrosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial nephritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 3 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric obstruction | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric stenosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urethral stenosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vesicoureteric reflux | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Hyperparathyroidism tertiary | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperparathyroidism | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthyroidism | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthralgia | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 4 / 7 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back pain | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrocalcinosis pyrophosphate | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondropathy | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fasciitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gouty arthritis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteonecrosis | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 3 / 8 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondrosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoporosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon disorder | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute hepatitis B | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute sinusitis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacteraemia | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 4 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriovenous fistula site infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis perforated | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary tract infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colonic abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Catheter site infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Candida infection | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 8 / 551 (1.45%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 5 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cytomegalovirus colitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related sepsis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Disseminated tuberculosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device related infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gangrene | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fungal sepsis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Graft infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis salmonella | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 27 / 551 (4.90%) | 6 / 273 (2.20%) | |
| occurrences causally related to treatment / all | 9 / 32 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Escherichia coli | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Legionella infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 551 (1.09%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 3 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster disseminated | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes zoster | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 6 / 7 | 1 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic cyst infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes oesophagitis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis bacterial | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis tuberculous | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Localised infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 3 / 4 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymph gland infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Liver abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lobar pneumonia | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ophthalmic herpes zoster | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media chronic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis media | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Necrotising fasciitis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis bacterial | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia haemophilus | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |
| subjects affected / exposed | 64 / 551 (11.62%) | 12 / 273 (4.40%) | |
| occurrences causally related to treatment / all | 35 / 75 | 6 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngeal abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis infective | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound infection | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 6 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary mycosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary tuberculosis | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 4 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 11 / 551 (2.00%) | 6 / 273 (2.20%) | |
| occurrences causally related to treatment / all | 5 / 13 | 2 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 11 / 551 (2.00%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 9 / 13 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyuria | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal abscess | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal abscess | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 7 / 551 (1.27%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 8 / 10 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salmonellosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic abscess | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Streptococcal bacteraemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tinea pedis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculous pleurisy | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculosis | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicella | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral diarrhoea | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 3 / 8 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound infection | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 4 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 42 / 551 (7.62%) | 14 / 273 (5.13%) | |
| occurrences causally related to treatment / all | 17 / 54 | 1 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 6 / 551 (1.09%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 6 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Septic shock | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 1 / 5 | 1 / 1 | |
| deaths causally related to treatment / all | 3 / 3 | 0 / 0 | |
| Bronchopneumonia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 8 / 551 (1.45%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 5 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 14 / 551 (2.54%) | 4 / 273 (1.47%) | |
| occurrences causally related to treatment / all | 9 / 25 | 1 / 4 | |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 17 / 551 (3.09%) | 6 / 273 (2.20%) | |
| occurrences causally related to treatment / all | 14 / 28 | 4 / 8 | |
| deaths causally related to treatment / all | 2 / 3 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Calciphylaxis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Electrolyte imbalance | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 5 / 551 (0.91%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 1 / 7 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dehydration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 15 / 551 (2.72%) | 3 / 273 (1.10%) | |
| occurrences causally related to treatment / all | 6 / 19 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid overload | | | |
| subjects affected / exposed | 3 / 551 (0.54%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 2 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 2 / 273 (0.73%) | |
| occurrences causally related to treatment / all | 0 / 2 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypervolaemia | | | |
| subjects affected / exposed | 2 / 551 (0.36%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 551 (0.18%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypovolaemia | | | |
| subjects affected / exposed | 4 / 551 (0.73%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 1 / 551 (0.18%) | 0 / 273 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 551 (0.00%) | 1 / 273 (0.37%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| **Non-serious adverse events** | SRL Conversion in Stable Renal Transplant Recipients | CNI Continuation in Stable Renal Transplant Recipients | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 542 / 551 (98.37%) | 258 / 273 (94.51%) | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 120 / 551 (21.78%) | 67 / 273 (24.54%) | |
| occurrences (all) | 215 | 125 | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 36 / 551 (6.53%) | 20 / 273 (7.33%) | |
| occurrences (all) | 43 | 34 | |
| Asthenia | | | |
| subjects affected / exposed | 39 / 551 (7.08%) | 13 / 273 (4.76%) | |
| occurrences (all) | 55 | 16 | |
| Oedema peripheral | | | |
| subjects affected / exposed | 196 / 551 (35.57%) | 52 / 273 (19.05%) | |
| occurrences (all) | 551 | 111 | |
| Fatigue | | | |
| subjects affected / exposed | 51 / 551 (9.26%) | 21 / 273 (7.69%) | |
| occurrences (all) | 80 | 35 | |
| Oedema | | | |
| subjects affected / exposed | 67 / 551 (12.16%) | 23 / 273 (8.42%) | |
| occurrences (all) | 119 | 35 | |
| Pyrexia | | | |
| subjects affected / exposed | 120 / 551 (21.78%) | 26 / 273 (9.52%) | |
| occurrences (all) | 173 | 40 | |
| Reproductive system and breast disorders | | | |
| Amenorrhoea | | | |
| subjects affected / exposed | 15 / 551 (2.72%) | 1 / 273 (0.37%) | |
| occurrences (all) | 24 | 1 | |
| Erectile dysfunction | | | |
| subjects affected / exposed | 25 / 551 (4.54%) | 8 / 273 (2.93%) | |
| occurrences (all) | 52 | 15 | |
| Menorrhagia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 11 / 551 (2.00%) | 2 / 273 (0.73%) | |
| occurrences (all) | 19 | 2 | |
| Ovarian cyst | | | |
| subjects affected / exposed | 13 / 551 (2.36%) | 2 / 273 (0.73%) | |
| occurrences (all) | 33 | 4 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 116 / 551 (21.05%) | 42 / 273 (15.38%) | |
| occurrences (all) | 170 | 66 | |
| Dyspnoea | | | |
| subjects affected / exposed | 51 / 551 (9.26%) | 21 / 273 (7.69%) | |
| occurrences (all) | 79 | 36 | |
| Epistaxis | | | |
| subjects affected / exposed | 53 / 551 (9.62%) | 6 / 273 (2.20%) | |
| occurrences (all) | 82 | 7 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 42 / 551 (7.62%) | 11 / 273 (4.03%) | |
| occurrences (all) | 45 | 13 | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 34 / 551 (6.17%) | 14 / 273 (5.13%) | |
| occurrences (all) | 66 | 25 | |
| Insomnia | | | |
| subjects affected / exposed | 42 / 551 (7.62%) | 17 / 273 (6.23%) | |
| occurrences (all) | 81 | 27 | |
| Investigations | | | |
| Blood cholesterol increased | | | |
| subjects affected / exposed | 61 / 551 (11.07%) | 6 / 273 (2.20%) | |
| occurrences (all) | 152 | 14 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 44 / 551 (7.99%) | 2 / 273 (0.73%) | |
| occurrences (all) | 81 | 2 | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 50 / 551 (9.07%) | 4 / 273 (1.47%) | |
| occurrences (all) | 83 | 7 | |
| Blood lactate dehydrogenase | | | |

| | | | |
|---|---|---|---|
| increased | | | |
| subjects affected / exposed | 72 / 551 (13.07%) | 6 / 273 (2.20%) | |
| occurrences (all) | 129 | 9 | |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 68 / 551 (12.34%) | 8 / 273 (2.93%) | |
| occurrences (all) | 161 | 15 | |
| Low density lipoprotein increased | | | |
| subjects affected / exposed | 37 / 551 (6.72%) | 8 / 273 (2.93%) | |
| occurrences (all) | 73 | 19 | |
| Weight decreased | | | |
| subjects affected / exposed | 32 / 551 (5.81%) | 11 / 273 (4.03%) | |
| occurrences (all) | 41 | 19 | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 109 / 551 (19.78%) | 48 / 273 (17.58%) | |
| occurrences (all) | 239 | 96 | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 117 / 551 (21.23%) | 45 / 273 (16.48%) | |
| occurrences (all) | 253 | 70 | |
| Dizziness | | | |
| subjects affected / exposed | 38 / 551 (6.90%) | 16 / 273 (5.86%) | |
| occurrences (all) | 49 | 26 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 213 / 551 (38.66%) | 68 / 273 (24.91%) | |
| occurrences (all) | 582 | 147 | |
| Leukopenia | | | |
| subjects affected / exposed | 70 / 551 (12.70%) | 17 / 273 (6.23%) | |
| occurrences (all) | 134 | 21 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 71 / 551 (12.89%) | 12 / 273 (4.40%) | |
| occurrences (all) | 124 | 22 | |
| Gastrointestinal disorders | | | |
| Dyspepsia | | | |
| subjects affected / exposed | 32 / 551 (5.81%) | 21 / 273 (7.69%) | |
| occurrences (all) | 46 | 27 | |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 234 / 551 (42.47%) | 83 / 273 (30.40%) | |
| occurrences (all) | 530 | 140 | |
| Gastritis | | | |
| subjects affected / exposed | 20 / 551 (3.63%) | 17 / 273 (6.23%) | |
| occurrences (all) | 30 | 23 | |
| Abdominal pain | | | |
| subjects affected / exposed | 54 / 551 (9.80%) | 28 / 273 (10.26%) | |
| occurrences (all) | 67 | 37 | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 27 / 551 (4.90%) | 16 / 273 (5.86%) | |
| occurrences (all) | 36 | 23 | |
| Aphthous stomatitis | | | |
| subjects affected / exposed | 70 / 551 (12.70%) | 6 / 273 (2.20%) | |
| occurrences (all) | 154 | 12 | |
| Constipation | | | |
| subjects affected / exposed | 38 / 551 (6.90%) | 17 / 273 (6.23%) | |
| occurrences (all) | 52 | 24 | |
| Mouth ulceration | | | |
| subjects affected / exposed | 39 / 551 (7.08%) | 1 / 273 (0.37%) | |
| occurrences (all) | 66 | 1 | |
| Nausea | | | |
| subjects affected / exposed | 72 / 551 (13.07%) | 27 / 273 (9.89%) | |
| occurrences (all) | 101 | 44 | |
| Stomatitis | | | |
| subjects affected / exposed | 69 / 551 (12.52%) | 7 / 273 (2.56%) | |
| occurrences (all) | 87 | 8 | |
| Vomiting | | | |
| subjects affected / exposed | 73 / 551 (13.25%) | 37 / 273 (13.55%) | |
| occurrences (all) | 106 | 50 | |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus | | | |
| subjects affected / exposed | 29 / 551 (5.26%) | 4 / 273 (1.47%) | |
| occurrences (all) | 37 | 6 | |
| Rash | | | |
| subjects affected / exposed | 62 / 551 (11.25%) | 12 / 273 (4.40%) | |
| occurrences (all) | 103 | 17 | |

| | | | |
|---|---|---|---|
| Skin lesion | | | |
| subjects affected / exposed | 23 / 551 (4.17%) | 17 / 273 (6.23%) | |
| occurrences (all) | 34 | 62 | |
| Acne | | | |
| subjects affected / exposed | 95 / 551 (17.24%) | 10 / 273 (3.66%) | |
| occurrences (all) | 214 | 18 | |
| Renal and urinary disorders | | | |
| Renal impairment | | | |
| subjects affected / exposed | 30 / 551 (5.44%) | 23 / 273 (8.42%) | |
| occurrences (all) | 60 | 54 | |
| Dysuria | | | |
| subjects affected / exposed | 30 / 551 (5.44%) | 12 / 273 (4.40%) | |
| occurrences (all) | 44 | 16 | |
| Haematuria | | | |
| subjects affected / exposed | 35 / 551 (6.35%) | 11 / 273 (4.03%) | |
| occurrences (all) | 59 | 15 | |
| Proteinuria | | | |
| subjects affected / exposed | 159 / 551 (28.86%) | 43 / 273 (15.75%) | |
| occurrences (all) | 365 | 92 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 91 / 551 (16.52%) | 54 / 273 (19.78%) | |
| occurrences (all) | 180 | 113 | |
| Back pain | | | |
| subjects affected / exposed | 51 / 551 (9.26%) | 37 / 273 (13.55%) | |
| occurrences (all) | 73 | 71 | |
| Muscle spasms | | | |
| subjects affected / exposed | 21 / 551 (3.81%) | 18 / 273 (6.59%) | |
| occurrences (all) | 25 | 24 | |
| Myalgia | | | |
| subjects affected / exposed | 38 / 551 (6.90%) | 12 / 273 (4.40%) | |
| occurrences (all) | 43 | 16 | |
| Pain in extremity | | | |
| subjects affected / exposed | 64 / 551 (11.62%) | 32 / 273 (11.72%) | |
| occurrences (all) | 101 | 50 | |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| Sinusitis | | | |
| subjects affected / exposed | 40 / 551 (7.26%) | 21 / 273 (7.69%) | |
| occurrences (all) | 63 | 30 | |
| Pneumonia | | | |
| subjects affected / exposed | 34 / 551 (6.17%) | 9 / 273 (3.30%) | |
| occurrences (all) | 42 | 10 | |
| Pharyngitis | | | |
| subjects affected / exposed | 54 / 551 (9.80%) | 24 / 273 (8.79%) | |
| occurrences (all) | 97 | 43 | |
| Oral herpes | | | |
| subjects affected / exposed | 39 / 551 (7.08%) | 9 / 273 (3.30%) | |
| occurrences (all) | 63 | 13 | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 69 / 551 (12.52%) | 37 / 273 (13.55%) | |
| occurrences (all) | 114 | 65 | |
| Influenza | | | |
| subjects affected / exposed | 70 / 551 (12.70%) | 36 / 273 (13.19%) | |
| occurrences (all) | 96 | 58 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 42 / 551 (7.62%) | 18 / 273 (6.59%) | |
| occurrences (all) | 51 | 21 | |
| Bronchitis | | | |
| subjects affected / exposed | 56 / 551 (10.16%) | 21 / 273 (7.69%) | |
| occurrences (all) | 71 | 27 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 109 / 551 (19.78%) | 54 / 273 (19.78%) | |
| occurrences (all) | 214 | 100 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 126 / 551 (22.87%) | 55 / 273 (20.15%) | |
| occurrences (all) | 281 | 114 | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 37 / 551 (6.72%) | 13 / 273 (4.76%) | |
| occurrences (all) | 45 | 19 | |
| Hypercholesterolaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 196 / 551 (35.57%) | 41 / 273 (15.02%) | |
| occurrences (all) | 583 | 94 | |
| Gout | | | |
| subjects affected / exposed | 29 / 551 (5.26%) | 16 / 273 (5.86%) | |
| occurrences (all) | 49 | 34 | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 58 / 551 (10.53%) | 12 / 273 (4.40%) | |
| occurrences (all) | 154 | 19 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 30 / 551 (5.44%) | 9 / 273 (3.30%) | |
| occurrences (all) | 56 | 17 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 63 / 551 (11.43%) | 19 / 273 (6.96%) | |
| occurrences (all) | 128 | 34 | |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 169 / 551 (30.67%) | 57 / 273 (20.88%) | |
| occurrences (all) | 546 | 152 | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 69 / 551 (12.52%) | 21 / 273 (7.69%) | |
| occurrences (all) | 151 | 44 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 16 / 551 (2.90%) | 18 / 273 (6.59%) | |
| occurrences (all) | 20 | 29 | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 47 / 551 (8.53%) | 46 / 273 (16.85%) | |
| occurrences (all) | 90 | 104 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 57 / 551 (10.34%) | 9 / 273 (3.30%) | |
| occurrences (all) | 97 | 12 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 19 August 2003 | Closed further study enrollment in the prospectively defined stratum of subjects with baseline Nankivell GFR of 20.0 to 40.0 mL/min. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|---|---|---|
| 19 August 2003 | Following the recommendations of the DSMB, enrollment of high risk subjects (GFR of 20.0 to 40.0 ml/min) was stopped. Beginning 19 Aug 2003, only subjects with baseline Nankivell GFR >40.0 mL/min could be randomly assigned to receive treatment. | - |

Notes:

### Limitations and caveats

None reported