



Clinical trial results:

A Phase 3, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With Lumacaftor in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation

Summary

| | |
|--------------------------|----------------------------------|
| EudraCT number | 2013-000604-41 |
| Trial protocol | IT CZ SE AT BE GB DE NL ES IE DK |
| Global end of trial date | 07 April 2016 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 23 October 2016 |
| First version publication date | 23 October 2016 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | VX12-809-105 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01931839 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Vertex Pharmaceuticals Incorporated |
| Sponsor organisation address | 50 Northern Avenue, Boston, Massachusetts, United States, 02210-1862 |
| Public contact | Medical Monitor, Vertex Pharmaceuticals Incorporated, + 1 617-341-6777, medicalinfo@vrtx.com |
| Scientific contact | Medical Monitor, Vertex Pharmaceuticals Incorporated, + 1 617-341-6777, medicalinfo@vrtx.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001582-PIP01-13 |
| 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 | 08 June 2016 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 April 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long term safety and tolerability of lumacaftor (LUM) in combination with ivacaftor (IVA) in subjects with cystic fibrosis (CF), homozygous or heterozygous for the F508del-cystic fibrosis transmembrane conductance regulator (CFTR) mutation, who were in the Part A and Part B Treatment Cohorts.

Protection of trial subjects:

The study was conducted in accordance with the ethical principles stated in the Declaration of Helsinki and the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP)

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 24 October 2013 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Safety |
| Long term follow-up duration | 2 Years |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 103 |
| Country: Number of subjects enrolled | Austria: 9 |
| Country: Number of subjects enrolled | Belgium: 36 |
| Country: Number of subjects enrolled | Canada: 41 |
| Country: Number of subjects enrolled | Czech Republic: 14 |
| Country: Number of subjects enrolled | Denmark: 9 |
| Country: Number of subjects enrolled | France: 70 |
| Country: Number of subjects enrolled | Germany: 83 |
| Country: Number of subjects enrolled | Ireland: 13 |
| Country: Number of subjects enrolled | Italy: 51 |
| Country: Number of subjects enrolled | Netherlands: 18 |
| Country: Number of subjects enrolled | Spain: 19 |
| Country: Number of subjects enrolled | Sweden: 7 |
| Country: Number of subjects enrolled | United States: 649 |
| Country: Number of subjects enrolled | United Kingdom: 41 |
| Worldwide total number of subjects | 1163 |
| EEA total number of subjects | 370 |

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) | 283 |
| Adults (18-64 years) | 880 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study conducted in 2 parts: A and B. Part A consisted of Treatment Cohorts and an Observational Cohort, which enrolled subjects from Study VX12-809-103 and Study VX12-809-104. Part B consisted of Treatment Cohorts which enrolled subjects from Cohort 4 of Study VX09-809-102. Of 1164 subjects enrolled, 1163 were dosed and included in EudraCT results.

Pre-assignment

Screening details:

As per planned analysis, endpoint evaluation may also include subjects from the parent study VX12-809-103 (2012-003989-40), VX12-809-104 (2012-003990-24) or Cohort 4 of VX09-809-102 (2010-020413-90) irrespective of whether they were enrolled in the current study or not.

Period 1

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

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h |

Arm description:

Subjects who received LUM 600 milligram (mg) once daily (qd) in fixed dose combination with IVA 250 mg every 12 hours (q12h) in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Lumacaftor Plus Ivacaftor Combination |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

LUM 600 mg plus IVA 250 mg as a fixed dose combination in morning up to Week 96.

| | |
|--|--------------------|
| Investigational medicinal product name | Ivacaftor |
| Investigational medicinal product code | VX-770 |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Ivacaftor 250 mg in evening up to Week 96.

| | |
|------------------|---|
| Arm title | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h |
|------------------|---|

Arm description:

Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96.

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

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Lumacaftor Plus Ivacaftor Combination |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

LUM 600 mg plus IVA 250 mg as a fixed dose combination in morning up to Week 96.

| | |
|--|--------------------|
| Investigational medicinal product name | Ivacaftor |
| Investigational medicinal product code | VX-770 |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Ivacaftor 250 mg in evening up to Week 96.

| | |
|------------------|--|
| Arm title | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h |
|------------------|--|

Arm description:

Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Lumacaftor Plus Ivacaftor Combination |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

LUM 400 mg plus IVA 250 mg as a fixed dose combination in morning and evening up to Week 96.

| | |
|------------------|---|
| Arm title | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|------------------|---|

Arm description:

Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Lumacaftor Plus Ivacaftor Combination |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

LUM 400 mg plus IVA 250 mg as a fixed dose combination in morning and evening up to Week 96.

| | |
|------------------|------------------------------------|
| Arm title | Arm 5: Part A Observational Cohort |
|------------------|------------------------------------|

Arm description:

Subjects who received either LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h or LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h or placebo matched to LUM and IVA q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), were observed (did not receive study drug) in this study VX12-809-105 (2013-000604-41) for up to 2 years.

| | |
|---|-----------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| | |
|------------------|--|
| Arm title | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h |
|------------------|--|

Arm description:

Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received the same treatment in this VX12-809-

105 (2013-000604-41) up to Week 96.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Lumacaftor Plus Ivacaftor Combination |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

LUM 400 mg plus IVA 250 mg as a fixed dose combination in morning and evening up to Week 96.

| | |
|------------------|---|
| Arm title | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|------------------|---|

Arm description:

Subjects who received placebo matched to LUM and IVA tablet in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Lumacaftor Plus Ivacaftor Combination |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

LUM 400 mg plus IVA 250 mg as a fixed dose combination in morning and evening up to Week 96.

| Number of subjects in period 1 | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h |
|---------------------------------------|--|---|--|
| Started | 335 | 178 | 340 |
| Completed | 294 | 152 | 301 |
| Not completed | 41 | 26 | 39 |
| Physician decision | 1 | - | 1 |
| Other | 4 | 2 | 6 |
| Death | - | 1 | 2 |
| Adverse event | 9 | 4 | 1 |
| Withdrawal of consent | - | - | - |
| Lost to follow-up | 1 | 2 | 4 |
| Other non-compliance | 15 | 9 | 12 |
| Withdrawal of consent (not due to AE) | 11 | 8 | 13 |

| Number of subjects in period 1 | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | Arm 5: Part A Observational Cohort | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h |
|---------------------------------------|---|------------------------------------|--|
| Started | 176 | 19 | 55 |
| Completed | 162 | 18 | 50 |
| Not completed | 14 | 1 | 5 |
| Physician decision | - | - | - |

| | | | |
|---------------------------------------|---|---|---|
| Other | - | - | - |
| Death | - | - | - |
| Adverse event | 3 | - | - |
| Withdrawal of consent | - | 1 | - |
| Lost to follow-up | 5 | - | - |
| Other non-compliance | 3 | - | 3 |
| Withdrawal of consent (not due to AE) | 3 | - | 2 |

| Number of subjects in period 1 | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|---------------------------------------|--|
| Started | 60 |
| Completed | 56 |
| Not completed | 4 |
| Physician decision | 1 |
| Other | - |
| Death | - |
| Adverse event | 1 |
| Withdrawal of consent | - |
| Lost to follow-up | - |
| Other non-compliance | - |
| Withdrawal of consent (not due to AE) | 2 |

Baseline characteristics

Reporting groups

| | |
|--|---|
| Reporting group title | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h |
| Reporting group description: Subjects who received LUM 600 milligram (mg) once daily (qd) in fixed dose combination with IVA 250 mg every 12 hours (q12h) in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h |
| Reporting group description: Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 5: Part A Observational Cohort |
| Reporting group description: Subjects who received either LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h or LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h or placebo matched to LUM and IVA q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), were observed (did not receive study drug) in this study VX12-809-105 (2013-000604-41) for up to 2 years. | |
| Reporting group title | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received the same treatment in this VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received placebo matched to LUM and IVA tablet in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |

| Reporting group values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h |
|---|--|---|--|
| Number of subjects | 335 | 178 | 340 |
| Age categorical Units: Subjects | | | |
| Age continuous Units: years arithmetic mean standard deviation | 24.1 ± 8.97 | 25.7 ± 10.74 | 25.1 ± 9.35 |

| | | | |
|---------------------------------------|-----|----|-----|
| Gender categorical Units: Subjects | | | |
| Female | 166 | 89 | 164 |
| Male | 169 | 89 | 176 |

| | | | |
|------------------------------------|--|---------------------------------------|--|
| Reporting group values | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | Arm 5: Part A Observational Cohort | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h |
| Number of subjects | 176 | 19 | 55 |
| Age categorical Units: Subjects | | | |

| | | | |
|---------------------------------------|--------|---------|--------|
| Age continuous Units: years | | | |
| arithmetic mean | 24.9 | 27.2 | 29.3 |
| standard deviation | ± 10.1 | ± 11.08 | ± 7.82 |
| Gender categorical Units: Subjects | | | |
| Female | 86 | 12 | 25 |
| Male | 90 | 7 | 30 |

| | | | |
|------------------------------------|--|-------|--|
| Reporting group values | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | Total | |
| Number of subjects | 60 | 1163 | |
| Age categorical Units: Subjects | | | |

| | | | |
|---------------------------------------|--------|-----|--|
| Age continuous Units: years | | | |
| arithmetic mean | 31 | | |
| standard deviation | ± 8.98 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 31 | 573 | |
| Male | 29 | 590 | |

End points

End points reporting groups

| | |
|--|---|
| Reporting group title | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h |
| Reporting group description: Subjects who received LUM 600 milligram (mg) once daily (qd) in fixed dose combination with IVA 250 mg every 12 hours (q12h) in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h |
| Reporting group description: Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 5: Part A Observational Cohort |
| Reporting group description: Subjects who received either LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h or LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h or placebo matched to LUM and IVA q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), were observed (did not receive study drug) in this study VX12-809-105 (2013-000604-41) for up to 2 years. | |
| Reporting group title | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Reporting group title | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
| Reporting group description: Subjects who received placebo matched to LUM and IVA tablet in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Subject analysis set title | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Subjects who were randomized to LUM 600 milligram (mg) once daily (qd) in fixed dose combination with IVA 250 mg every 12 hours (q12h) in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24). | |
| Subject analysis set title | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Subjects who were randomized to placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96. | |
| Subject analysis set title | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Subjects who were randomized to LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in | |

the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24).

| | |
|----------------------------|---|
| Subject analysis set title | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects who were randomized to placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96.

| | |
|----------------------------|--|
| Subject analysis set title | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects who were randomized to LUM 400 mg q12h in fixed dose combination with IVA 250 q12h in Cohort 4 of the previous study VX09-809-102 (2010-020413-90).

| | |
|----------------------------|---|
| Subject analysis set title | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Subjects who were randomized to placebo matched to LUM and IVA tablet in Cohort 4 of the previous study VX09-809-102 (2010-020413-90).

Primary: Part A Treatment Cohort: Number of Subjects With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs)

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Number of Subjects With Treatment-Emergent Adverse Events (AEs) and Serious Adverse Events (SAEs) ^{[1][2]} |
|-----------------|--|

End point description:

AE: as any untoward medical occurrence in a subject during the study; the event does not necessarily have a causal relationship with the treatment. This includes any newly occurring event or previous condition that has increased in severity or frequency after informed consent form is signed. AE includes serious as well as non-serious AEs. SAE (subset of AE): medical event or condition, which falls into any of the following categories, regardless of its relationship to the study drug: death, life threatening adverse experience, In-patient hospitalization/prolongation of hospitalization, persistent/significant disability or incapacity, congenital anomaly/birth defect, important medical event. Any AE that increased in severity or newly developed at or after initial dosing of study drug to 28 days after last dose of study drug was considered treatment-emergent. Safety Set (study 105) included all subjects in Treatment Cohort Part A who were exposed to any amount of study drug.

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

End point timeframe:

Day 1 up to Week 105

Notes:

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

Justification: Only descriptive statistics were reported, inferential statistics were not planned for primary endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|-----------------------------|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 335 | 178 | 340 | 176 |
| Units: subjects | | | | |
| Subjects with AEs | 331 | 177 | 333 | 176 |
| Subjects with SAEs | 156 | 77 | 143 | 89 |

Statistical analyses

No statistical analyses for this end point

Primary: Part B Treatment Cohort: Number of Subjects With Treatment-Emergent AEs and SAEs

| | |
|-----------------|--|
| End point title | Part B Treatment Cohort: Number of Subjects With Treatment-Emergent AEs and SAEs ^[3] ^[4] |
|-----------------|--|

End point description:

AE: as any untoward medical occurrence in a subject during the study; the event does not necessarily have a causal relationship with the treatment. This includes any newly occurring event or previous condition that has increased in severity or frequency after informed consent form is signed. AE includes serious as well as non-serious AEs. SAE (subset of AE): medical event or condition, which falls into any of the following categories, regardless of its relationship to the study drug: death, life threatening adverse experience, In-patient hospitalization/prolongation of hospitalization, persistent/significant disability or incapacity, congenital anomaly/birth defect, important medical event. Any AE that increased in severity or newly developed at or after initial dosing of study drug to 28 days after last dose of study drug was considered treatment-emergent. Safety Set (study 105) included all subjects in the Treatment Cohort Part B who were exposed to any amount of study drug.

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

End point timeframe:

Day 1 up to Week 105

Notes:

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

Justification: Only descriptive statistics were reported, inferential statistics were not planned for primary endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
|-----------------------------|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 55 | 60 | | |
| Units: subjects | | | | |
| Subjects with AEs | 52 | 57 | | |
| Subjects with SAEs | 18 | 21 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Absolute Change From Baseline in Percent Predicted Forced Expiratory Volume in 1 Second (FEV1) At Day 15, Week 8, 16, 24,

36, 48, 60 and 72

| | |
|-----------------|---|
| End point title | Part A Treatment Cohort: Absolute Change From Baseline in Percent Predicted Forced Expiratory Volume in 1 Second (FEV1) At Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[5] |
|-----------------|---|

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Hankinson and Wang standards were used to calculate percent predicted FEV1 (for age, gender, race, and height). The Hankinson standard was used for male subjects 18 years and older and female subjects 16 years and older. The Wang standard was used for male subjects aged 12 to 17 years and for female subjects aged 12 to 15 years. Full Analysis Set (FAS) study 105 (2013-000604-41) included all subjects randomized in the Part A Treatment Cohort and dosed. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) and Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 103/104/105); Day 15, Week 8, 16, 24, 36, 48, 60 , 72 (Study 105)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|--|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 319 | 173 | 317 | 165 |
| Units: percent predicted of FEV1 | | | | |
| least squares mean (standard error) | | | | |
| Absolute Change at Day 15 (n= 319, 173, 317, 165) | 3 (± 0.5) | 2.8 (± 0.6) | 2.8 (± 0.5) | 3 (± 0.6) |
| Absolute Change at Week 8 (n= 309, 164, 316, 165) | 3.1 (± 0.5) | 2.8 (± 0.6) | 3.4 (± 0.5) | 4.2 (± 0.6) |
| Absolute Change at Week 16 (n= 307, 166, 313, 160) | 2.6 (± 0.5) | 2.7 (± 0.6) | 2.5 (± 0.5) | 3.6 (± 0.7) |
| Absolute Change at Week 24 (n= 291, 158, 295, 154) | 2.9 (± 0.5) | 2.4 (± 0.6) | 2.7 (± 0.5) | 3.4 (± 0.7) |
| Absolute Change at Week 36 (n= 292, 155, 294, 150) | 2.7 (± 0.5) | 2.2 (± 0.7) | 1.9 (± 0.5) | 3.1 (± 0.7) |
| Absolute Change at Week 48 (n= 279, 153, 286, 143) | 1.5 (± 0.5) | 1.8 (± 0.7) | 1.4 (± 0.5) | 2.1 (± 0.7) |
| Absolute Change at Week 60 (n= 276, 146, 282, 140) | 1.7 (± 0.5) | 2.1 (± 0.7) | 1.6 (± 0.5) | 1.4 (± 0.7) |
| Absolute Change at Week 72 (n= 275, 146, 273, 134) | 1.2 (± 0.5) | 1.9 (± 0.7) | 0.5 (± 0.5) | 1.5 (± 0.7) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B Treatment Cohort: Absolute Change From Baseline in Percent Predicted FEV1 at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|--|
| End point title | Part B Treatment Cohort: Absolute Change From Baseline in Percent Predicted FEV1 at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[6] |
|-----------------|--|

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Hankinson and Wang standards were used to calculate percent predicted FEV1 (for age, gender, race, and height). The Hankinson standard was used for male subjects 18 years and older and female subjects 16 years and older. The Wang standard was used for male subjects aged 12 to 17 years and for female subjects aged 12 to 15 years. FAS (study 105) included all subjects randomized in the Part B Treatment Cohort and dosed. Analysis was performed using baseline of Cohort 4 of previous study VX09-809-102 (2010-020413-90) for Arm 6 and 7. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 102), Day 15, Week 8, 16, 24, 36, 48, 60 , 72 (Study 105)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
|--|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 52 | 57 | | |
| Units: percent predicted of FEV1 | | | | |
| arithmetic mean (standard deviation) | | | | |
| Absolute Change at Day 15 (n= 52, 57) | -2 (± 8) | -3.4 (± 6.6) | | |
| Absolute Change at Week 8 (n= 49, 55) | -3.9 (± 7.4) | -1.8 (± 6.4) | | |
| Absolute Change at Week 16 (n= 50, 52) | -3.1 (± 9) | -2.8 (± 6.8) | | |
| Absolute Change at Week 24 (n= 36, 36) | -2.9 (± 7.7) | -2.5 (± 7.3) | | |
| Absolute Change at Week 36 (n= 20, 19) | -3.2 (± 7.9) | -2.3 (± 7.9) | | |
| Absolute Change at Week 48 (n= 15, 17) | -5.4 (± 11.2) | -2 (± 6) | | |
| Absolute Change at Week 60 (n= 12, 16) | -1.8 (± 10.1) | -1.9 (± 8.2) | | |
| Absolute Change at Week 72 (n= 11, 15) | -2.8 (± 9.2) | -7.8 (± 8.3) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Relative Change From Baseline in Percent Predicted FEV1 at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Relative Change From Baseline in Percent Predicted FEV1 at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[7] |
|-----------------|--|

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Hankinson

and Wang standards were used to calculate percent predicted FEV1 (for age, gender, race, and height). The Hankinson standard was used for male subjects 18 years and older and female subjects 16 years and older. The Wang standard was used for male subjects aged 12 to 17 years and for female subjects aged 12 to 15 years. FAS study 105 (2013-000604-41) included all subjects randomized in the Part A Treatment Cohort and dosed. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) and Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 103/104/105), Day 15, Week 8, 16, 24, 36, 48, 60 , 72 (Study 105)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|--|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 319 | 173 | 317 | 165 |
| Units: percent change | | | | |
| least squares mean (standard error) | | | | |
| Relative Change at Day 15 (n= 319, 173, 317, 165) | 5.3 (± 0.9) | 5.1 (± 1.2) | 5.3 (± 0.9) | 4.8 (± 1.2) |
| Relative Change at Week 8 (n= 309, 164, 316, 165) | 5.6 (± 0.9) | 5.6 (± 1.2) | 6.2 (± 0.9) | 7.1 (± 1.2) |
| Relative Change at Week 16 (n= 307, 166, 313, 160) | 4.9 (± 0.9) | 5.4 (± 1.2) | 4.8 (± 0.9) | 6.5 (± 1.2) |
| Relative Change at Week 24 (n= 291, 158, 295, 154) | 5.1 (± 0.9) | 4.9 (± 1.2) | 5 (± 0.9) | 6.1 (± 1.2) |
| Relative Change at Week 36 (n= 292, 155, 294, 150) | 4.7 (± 0.9) | 4 (± 1.2) | 3.6 (± 0.9) | 5.5 (± 1.2) |
| Relative Change at Week 48 (n= 279, 153, 286, 143) | 2.7 (± 0.9) | 3.6 (± 1.2) | 2.9 (± 0.9) | 3.6 (± 1.2) |
| Relative Change at Week 60 (n= 276, 146, 282, 140) | 2.9 (± 0.9) | 4.1 (± 1.2) | 2.7 (± 0.9) | 3.1 (± 1.2) |
| Relative Change at Week 72 (n= 275, 146, 273, 134) | 2.4 (± 0.9) | 3.8 (± 1.2) | 1.4 (± 0.9) | 2.6 (± 1.2) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B Treatment Cohort: Relative Change From Baseline in Percent Predicted FEV1 at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|--|
| End point title | Part B Treatment Cohort: Relative Change From Baseline in Percent Predicted FEV1 at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[8] |
|-----------------|--|

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Hankinson and Wang standards were used to calculate percent predicted FEV1 (for age, gender, race, and height). The Hankinson standard was used for male subjects 18 years and older and female subjects 16 years and older. The Wang standard was used for male subjects aged 12 to 17 years and for female subjects

aged 12 to 15 years. FAS (study 105) included all subjects randomized in the Part B Treatment Cohort and dosed. Analysis was performed using baseline of Cohort 4 of previous study VX09-809-102 (2010-020413-90) for Arm 6 and 7. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 102), Day 15, Week 8, 16, 24, 36, 48, 60 , 72 (Study 105)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
|--|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 52 | 57 | | |
| Units: percent change | | | | |
| arithmetic mean (standard deviation) | | | | |
| Relative Change at Day 15 (n= 52, 57) | -2.2 (± 13.6) | -5.8 (± 11.4) | | |
| Relative Change at Week 8 (n= 49, 55) | -5.2 (± 12.8) | -3.1 (± 11.4) | | |
| Relative Change at Week 16 (n= 50, 52) | -4.2 (± 15.8) | -4.9 (± 11.8) | | |
| Relative Change at Week 24 (n= 36, 36) | -3.4 (± 13.2) | -4.2 (± 12.6) | | |
| Relative Change at Week 36 (n= 20, 19) | -4.1 (± 12.5) | -3.5 (± 14.2) | | |
| Relative Change at Week 48 (n= 15, 17) | -6.9 (± 15.9) | -2.8 (± 10.6) | | |
| Relative Change at Week 60 (n= 12, 16) | -0.7 (± 16.6) | -2.6 (± 13.9) | | |
| Relative Change at Week 72 (n= 11, 15) | -3.3 (± 13.3) | -11.8 (± 10.7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Absolute Change From Baseline in Body Mass Index (BMI) at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|---|
| End point title | Part A Treatment Cohort: Absolute Change From Baseline in Body Mass Index (BMI) at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[9] |
|-----------------|---|

End point description:

BMI = (Weight in kilogram [kg]) divided by (Stature in meters [m]) ^2. FAS study 105 (2013-000604-41) included all subjects randomized in the Part A Treatment Cohort and dosed. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) and Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 103/104/105), Day 15, Week 8, 16, 24, 36, 48, 60 , 72 (Study 105)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|---|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 329 | 178 | 338 | 175 |
| Units: Kilogram per square meter (kg/m ²) | | | | |
| least squares mean (standard error) | | | | |
| Absolute Change at Day 15 (n= 328, 178, 338, 175) | 0.56 (± 0.06) | 0.06 (± 0.08) | 0.5 (± 0.06) | 0.1 (± 0.08) |
| Absolute Change at Week 8 (n= 329, 173, 331, 172) | 0.58 (± 0.06) | 0.14 (± 0.08) | 0.55 (± 0.06) | 0.27 (± 0.08) |
| Absolute Change at Week 16 (n= 321, 173, 325, 170) | 0.58 (± 0.06) | 0.19 (± 0.08) | 0.53 (± 0.06) | 0.35 (± 0.08) |
| Absolute Change at Week 24 (n= 312, 169, 319, 165) | 0.61 (± 0.06) | 0.22 (± 0.08) | 0.62 (± 0.06) | 0.41 (± 0.08) |
| Absolute Change at Week 36 (n= 304, 165, 315, 160) | 0.66 (± 0.06) | 0.33 (± 0.08) | 0.72 (± 0.06) | 0.59 (± 0.08) |
| Absolute Change at Week 48 (n= 299, 162, 307, 151) | 0.63 (± 0.06) | 0.42 (± 0.08) | 0.71 (± 0.06) | 0.62 (± 0.09) |
| Absolute Change at Week 60 (n= 296, 158, 298, 147) | 0.71 (± 0.06) | 0.54 (± 0.08) | 0.8 (± 0.06) | 0.62 (± 0.09) |
| Absolute Change at Week 72 (n= 287, 152, 289, 145) | 0.72 (± 0.06) | 0.52 (± 0.08) | 0.69 (± 0.06) | 0.62 (± 0.09) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B Treatment Cohort: Absolute Change From Baseline in BMI at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|--|--|
| End point title | Part B Treatment Cohort: Absolute Change From Baseline in BMI at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[10] |
| End point description: BMI = (Weight [in kg]) divided by (Stature [in meters]) ² . FAS (study 105) included all subjects randomized in the Part B Treatment Cohort and dosed. Analysis was performed using baseline of Cohort 4 of previous study VX09-809-102 (2010-020413-90) for Arm 6 and 7. Here "n" = those subjects who were evaluable at the specified time points for each arm, respectively. | |
| End point type | Secondary |

End point timeframe:

Baseline (Study 102), Day 15, Week 8, 16, 24, 36, 48, 60 , 72 (Study 105)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only arms which are applicable to the endpoint are reported.

| | | | | |
|--|---|---|--|--|
| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 55 | 60 | | |
| Units: kg/m ² | | | | |
| arithmetic mean (standard deviation) | | | | |
| Absolute Change at Day 15 (n= 55, 60) | -0.05 (± 0.52) | -0.03 (± 0.69) | | |
| Absolute Change at Week 8 (n= 54, 57) | -0.01 (± 0.82) | 0.14 (± 0.84) | | |
| Absolute Change at Week 16 (n= 51, 53) | 0.08 (± 1.02) | 0.2 (± 1.09) | | |
| Absolute Change at Week 24 (n= 39, 37) | 0.04 (± 0.92) | 0.14 (± 1.08) | | |
| Absolute Change at Week 36 (n= 20, 20) | 0.07 (± 0.54) | 0.85 (± 1.23) | | |
| Absolute Change at Week 48 (n= 17, 17) | 0.05 (± 0.64) | 0.81 (± 1.55) | | |
| Absolute Change at Week 60 (n= 12, 16) | 0.08 (± 0.7) | 0.58 (± 1.23) | | |
| Absolute Change at Week 72 (n= 13, 15) | 0.08 (± 0.71) | 0.41 (± 1.28) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Number of Pulmonary Exacerbations Events per Patient-Year

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Number of Pulmonary Exacerbations Events per Patient-Year |
|-----------------|--|

End point description:

Pulmonary exacerbation was defined as the treatment with new or changed antibiotic therapy (intravenous, inhaled, or oral) for greater than or equal to 4 sinopulmonary signs/symptoms. The number of events per patient year were reported, where patient years = total number of days on study/336. FAS (Study 103/104) was used for Arm 1 and 3, and included all subjects randomized in the previous studies and dosed. FAS (Study 105) was used for Arm 2 and 4, and included all subjects randomized in the Part A Treatment Cohort and dosed in current study 105. Analysis includes all events in the Cumulative Study Period for Arm 1 and 3, and all events in the Current Study period (Study 105) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint.

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

End point timeframe:

Baseline (Study 103/104) up to Week 100 (Study 105) for Arm 1 and 3 (Cumulative study period);
Baseline (Study 105) up to Week 100 (Study 105) for Arm 2 and 4 (current study period)

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|----------------------------------|--|---|--|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 368 | 179 | 369 | 176 |
| Units: events per patient year | | | | |
| number (confidence interval 95%) | 0.38 (0.32 to 0.46) | 0.42 (0.33 to 0.54) | 0.32 (0.26 to 0.38) | 0.37 (0.29 to 0.49) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Absolute Change From Baseline in Cystic Fibrosis Questionnaire – Revised (CFQ-R) Respiratory Domain Score at Day 15, Week 8, 16, 24, 48 and 72

| | |
|-----------------|---|
| End point title | Part A Treatment Cohort: Absolute Change From Baseline in Cystic Fibrosis Questionnaire – Revised (CFQ-R) Respiratory Domain Score at Day 15, Week 8, 16, 24, 48 and 72 ^[11] |
|-----------------|---|

End point description:

The CFQ-R is a validated subject-reported outcome measuring health-related quality of life for subjects with cystic fibrosis. Respiratory domain assessed respiratory symptoms (for example, coughing, congestion, wheezing), the scaled score range: 0-100; higher scores indicating fewer symptoms and better health-related quality of life. FAS study 105 (2013-000604-41) included all subjects randomized in the Part A Treatment Cohort and dosed. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) and Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 103/104/105), Day 15, Week 8, 16, 24, 48, 72 (Study 105)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|--|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 324 | 174 | 325 | 170 |
| Units: units on a scale | | | | |
| least squares mean (standard error) | | | | |
| Absolute Change at Day 15 (n= 324, 174, 325, 170) | 5.9 (± 0.9) | 2.3 (± 1.2) | 6.2 (± 0.9) | 3.5 (± 1.2) |
| Absolute Change at Week 8 (n= 323, 164, 319, 166) | 5 (± 0.9) | 4.1 (± 1.2) | 5.1 (± 0.9) | 6.8 (± 1.2) |
| Absolute Change at Week 16 (n= 313, 167, 312, 160) | 4.1 (± 0.9) | 2.8 (± 1.2) | 6.4 (± 0.9) | 7 (± 1.2) |
| Absolute Change at Week 24 (n= 305, 161, 304, 155) | 6 (± 0.9) | 3.8 (± 1.2) | 6.1 (± 0.9) | 4.7 (± 1.3) |

| | | | | |
|--|------------------|------------------|------------------|------------------|
| Absolute Change at Week 48 (n= 290, 152, 290, 140) | 2 (\pm 0.9) | 3.1 (\pm 1.3) | 3.7 (\pm 0.9) | 1.5 (\pm 1.3) |
| Absolute Change at Week 72 (n= 265, 141, 269, 135) | 3.2 (\pm 0.9) | 3.3 (\pm 1.3) | 5.7 (\pm 0.9) | 3.3 (\pm 1.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B Treatment Cohort: Absolute Change From Baseline in CFQ-R Respiratory Domain Score at Day 15, Week 8, 16, 24, 48 and 72

| | |
|-----------------|---|
| End point title | Part B Treatment Cohort: Absolute Change From Baseline in CFQ-R Respiratory Domain Score at Day 15, Week 8, 16, 24, 48 and 72 ^[12] |
|-----------------|---|

End point description:

The CFQ-R is a validated subject-reported outcome measuring health-related quality of life for subjects with cystic fibrosis. Respiratory domain assessed respiratory symptoms (for example, coughing, congestion, wheezing), the scaled score range: 0-100; higher scores indicating fewer symptoms and better health-related quality of life. FAS (study 105) included all subjects randomized in the Part B Treatment Cohort and dosed. Analysis was performed using baseline of Cohort 4 of previous study VX09-809-102 (2010-020413-90) for Arm 6 and 7. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 102 Study), Day 15, Week 8, 16, 24, 48, 72 (Study 105)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
|--|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 55 | 59 | | |
| Units: units on a scale | | | | |
| arithmetic mean (standard deviation) | | | | |
| Absolute Change at Day 15 (n= 55, 59) | 3.9 (\pm 18) | -4.1 (\pm 18.1) | | |
| Absolute Change at Week 8 (n= 54, 57) | 4.8 (\pm 18.6) | 1 (\pm 18.2) | | |
| Absolute Change at Week 16 (n= 51, 53) | 6.2 (\pm 17.2) | -0.2 (\pm 17) | | |
| Absolute Change at Week 24 (n= 39, 37) | 6.8 (\pm 19.1) | -1.2 (\pm 17.9) | | |
| Absolute Change at Week 48 (n= 19, 17) | 2 (\pm 14) | 4.9 (\pm 15.6) | | |
| Absolute Change at Week 72 (n= 13, 15) | 8.5 (\pm 21.8) | 2.2 (\pm 18.8) | | |

Statistical analyses

Secondary: Part A Treatment Cohort: Absolute Change From Baseline in BMI z-score at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Absolute Change From Baseline in BMI z-score at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[13] |
|-----------------|--|

End point description:

z-score is a statistical measure to evaluate how a single data point compares to a standard. It describes whether a mean was above or below the standard and how unusual the measurement is with range from -infinity to +infinity; 0: same mean, >0: a greater mean, and <0: a lesser mean than the standard. BMI-for-age z-score was calculated by using centers for disease control and prevention (CDC) growth charts for the pediatric population. FAS study 105 (2013-000604-41) included all subjects randomized in the Part A Treatment Cohort and dosed. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) and Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm,

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

End point timeframe:

Baseline (Study 103/104/105), Day 15, Week 8, 16, 24, 36, 48, 60, 72 (Study 105)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|--|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 117 | 56 | 109 | 60 |
| Units: z-score | | | | |
| least squares mean (standard error) | | | | |
| Absolute Change at Day 15 (n= 117, 56, 109, 60) | 0.16 (± 0.04) | -0.01 (± 0.06) | 0.14 (± 0.04) | -0.02 (± 0.05) |
| Absolute Change at Week 8 (n= 114, 53, 105, 60) | 0.15 (± 0.04) | 0.04 (± 0.06) | 0.16 (± 0.04) | 0.08 (± 0.05) |
| Absolute Change at Week 16 (n= 112, 53, 101, 58) | 0.12 (± 0.04) | 0.08 (± 0.06) | 0.15 (± 0.04) | 0.07 (± 0.05) |
| Absolute Change at Week 24 (n= 110, 49, 100, 56) | 0.14 (± 0.04) | 0.08 (± 0.06) | 0.17 (± 0.04) | 0.1 (± 0.05) |
| Absolute Change at Week 36 (n= 100, 46, 100, 52) | 0.14 (± 0.04) | 0.13 (± 0.06) | 0.16 (± 0.04) | 0.14 (± 0.05) |
| Absolute Change at Week 48 (n= 95, 46, 97, 47) | 0.09 (± 0.04) | 0.13 (± 0.06) | 0.11 (± 0.04) | 0.12 (± 0.06) |
| Absolute Change at Week 60 (n= 91, 45, 90, 44) | 0.11 (± 0.04) | 0.16 (± 0.06) | 0.14 (± 0.04) | 0.13 (± 0.06) |
| Absolute Change at Week 72 (n= 85, 45, 89, 42) | 0.06 (± 0.04) | 0.12 (± 0.06) | 0.04 (± 0.04) | 0.08 (± 0.06) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Absolute Change From Baseline in Body Weight at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Absolute Change From Baseline in Body Weight at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[14] |
|-----------------|--|

End point description:

Full Analysis Set (FAS) study 105 (2013-000604-41) included all subjects randomized in the Part A Treatment Cohort and dosed. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) and Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4. Here "Number of subjects analysed" = those subjects who were evaluable for this endpoint and "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

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

End point timeframe:

Baseline (Study 103/104/105), Day 15, Week 8, 16, 24, 36, 48, 60, 72 (Study 105)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|--|--|---|--|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 329 | 178 | 338 | 175 |
| Units: kilograms (kg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Absolute Change at Day 15 (n= 328, 178, 338, 175) | 1.7 (± 2.6) | -0.1 (± 1.8) | 1.3 (± 2.9) | 0.1 (± 1.2) |
| Absolute Change at Week 8 (n= 329, 173, 331, 172) | 1.8 (± 2.9) | 0.2 (± 2.1) | 1.5 (± 3.1) | 0.6 (± 1.9) |
| Absolute Change at Week 16 (n= 321, 173, 325, 170) | 1.9 (± 3.2) | 0.4 (± 2.6) | 1.6 (± 3.3) | 1 (± 2.5) |
| Absolute Change at Week 24 (n= 312, 169, 319, 165) | 2.2 (± 3.5) | 0.6 (± 2.6) | 2 (± 3.6) | 1.2 (± 2.8) |
| Absolute Change at Week 36 (n= 304, 165, 315, 160) | 2.3 (± 3.8) | 1 (± 3.4) | 2.4 (± 3.8) | 1.9 (± 3.4) |
| Absolute Change at Week 48 (n= 299, 162, 307, 151) | 2.4 (± 4.2) | 1.3 (± 3.7) | 2.5 (± 4.3) | 2.1 (± 3.7) |
| Absolute Change at Week 60 (n= 296, 158, 298, 147) | 2.7 (± 4.6) | 1.7 (± 4.2) | 2.9 (± 4.6) | 2.2 (± 4.4) |
| Absolute Change at Week 72 (n= 287, 152, 289, 145) | 2.9 (± 4.9) | 1.7 (± 4.8) | 2.7 (± 4.9) | 2.3 (± 4.7) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B Treatment Cohort: Absolute Change From Baseline in Body Weight at Day 15, Week 8, 16, 24, 36, 48, 60 and 72

| | |
|-----------------|--|
| End point title | Part B Treatment Cohort: Absolute Change From Baseline in Body Weight at Day 15, Week 8, 16, 24, 36, 48, 60 and 72 ^[15] |
|-----------------|--|

End point description:

FAS (study 105) included all subjects randomized in the Part B Treatment Cohort and dosed. Analysis

was performed using baseline of Cohort 4 of previous study VX09-809-102 (2010-020413-90) for Arm 6 and 7. Here "n" = those subjects who were evaluable at the specified time points for each arm, respectively.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Study 102), Day 15, Week 8, 16, 24, 36, 48, 60, 72 (Study 105) | |

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
|--|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 55 | 60 | | |
| Units: Kg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Absolute Change at Day 15 (n= 55, 60) | -0.1 (± 1.5) | -0.1 (± 1.8) | | |
| Absolute Change at Week 8 (n= 54, 57) | 0 (± 2.3) | 0.4 (± 2.3) | | |
| Absolute Change at Week 16 (n= 51, 53) | 0.3 (± 2.8) | 0.6 (± 2.9) | | |
| Absolute Change at Week 24 (n= 39, 37) | 0.2 (± 2.6) | 0.4 (± 3) | | |
| Absolute Change at Week 36 (n= 20, 20) | 0.3 (± 1.7) | 2.3 (± 3.3) | | |
| Absolute Change at Week 48 (n= 17, 17) | 0.2 (± 2) | 2.2 (± 4.3) | | |
| Absolute Change at Week 60 (n= 12, 16) | 0.3 (± 2.3) | 1.5 (± 3.3) | | |
| Absolute Change at Week 72 (n= 13, 15) | 0.2 (± 2.3) | 1.1 (± 3.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Time-to-First Pulmonary Exacerbation

| | |
|-----------------|---|
| End point title | Part A Treatment Cohort: Time-to-First Pulmonary Exacerbation |
|-----------------|---|

End point description:

Time-to-first pulmonary exacerbation was analyzed using the Kaplan-Meier estimates. Pulmonary exacerbation was defined as the treatment with new or changed antibiotic therapy (intravenous, inhaled, or oral) for greater than or equal to 4 sinopulmonary signs/symptoms. FAS (Study 103/104) was used for Arm 1 and 3, and included all subjects randomized in the previous studies and dosed. FAS (Study 105) was used for Arm 2 and 4, and included all subjects randomized in the Part A Treatment Cohort and dosed in current study 105. Analysis was performed for the the Cumulative Study Period for Arm 1 and 3, and for the current study period (Study 105) for Arm 2 and 4. Here, 99999 represents data for Q3 inter-quartile range was not available.

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

End point timeframe:

Baseline (Study 103/104) up to Week 100 (Study 105) for Arm 1 and 3 (Cumulative study period);
Baseline (Study 105) up to Week 100 (Study 105) for Arm 2 and 4 (current study period)

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|---------------------------------------|--|---|--|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 368 | 179 | 369 | 176 |
| Units: Days | | | | |
| median (inter-quartile range (Q1-Q3)) | 364 (99 to 99999) | 505 (111 to 99999) | 481 (132 to 99999) | 466 (153 to 99999) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Treatment Cohort: Percentage of Subjects With at Least 1 Pulmonary Exacerbation

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Percentage of Subjects With at Least 1 Pulmonary Exacerbation |
|-----------------|--|

End point description:

Pulmonary exacerbation was defined as the treatment with new or changed antibiotic therapy (intravenous, inhaled, or oral) for greater than or equal to 4 sinopulmonary signs/symptoms. FAS (Study 103/104) was used for Arm 1 and 3, and included all subjects randomized in the previous studies and dosed. FAS (Study 105) was used for Arm 2 and 4, and included all subjects randomized in the Part A Treatment Cohort and dosed in current study 105. Analysis was performed for the the Cumulative Study Period for Arm 1 and 3, and for the current study period (Study 105) for Arm 2 and 4.

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

End point timeframe:

Baseline (Study 103/104) up to Week 100 (Study 105) for Arm 1 and 3 (Cumulative study period);
Baseline (Study 105) up to Week 100 (Study 105) for Arm 2 and 4 (current study period)

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|----------------------------------|--|---|--|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 368 | 179 | 369 | 176 |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | 64.7 (59.8 to 69.6) | 53.6 (46.3 to 60.9) | 59.9 (54.9 to 64.9) | 55.7 (48.3 to 63) |

Statistical analyses

Secondary: Part A Treatment Cohort: Percentage of Subjects With Response Based on Relative Change in Percent Predicted FEV1 From Baseline

| | |
|-----------------|--|
| End point title | Part A Treatment Cohort: Percentage of Subjects With Response Based on Relative Change in Percent Predicted FEV1 From Baseline |
|-----------------|--|

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Hankinson and Wang standards were used to calculate percent predicted FEV1 (for age, gender, race, and height). Percentage of subjects with at least 5% and 10% relative change in percent predicted FEV1 from Baseline were reported. FAS (Study 103/104) was used for Arm 1 and 3, and included all subjects randomized in the previous studies and dosed. FAS (Study 105) was used for Arm 2 and 4, and included all subjects randomized in the Part A Treatment Cohort and dosed in current study 105. Analysis was performed using baseline of the previous study VX12-809-103 (2012-003989-40) or Study VX12-809-104 (2012-003990-24) for Arm 1 and 3. Analysis was performed using baseline of the current study VX12-809-105 (2013-000604-41) for Arm 2 and 4.

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

End point timeframe:

Baseline (Study 103/104/105); Day 15, Week 8, 16, 24, 36, 48, 60, 72, 84, 96 (Study 105)

| End point values | Arm 1: Part A - LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A - Placebo- LUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 4: Part A - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h |
|----------------------------------|--|---|--|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 368 | 179 | 369 | 176 |
| Units: Percentage of Subjects | | | | |
| number (confidence interval 95%) | | | | |
| Day 15: $\geq 5\%$ Change | 39.4 (34.4 to 44.4) | 42.5 (35.2 to 49.7) | 40.9 (35.9 to 45.9) | 42.6 (35.3 to 49.9) |
| Day 15: $\geq 10\%$ Change | 25 (20.6 to 29.4) | 26.8 (20.3 to 33.3) | 24.7 (20.3 to 29.1) | 26.7 (20.2 to 33.2) |
| Week 8: $\geq 5\%$ Change | 39.7 (34.7 to 44.7) | 38 (30.9 to 45.1) | 39.3 (34.3 to 44.3) | 48.9 (41.5 to 56.2) |
| Week 8: $\geq 10\%$ Change | 26.9 (22.4 to 31.4) | 23.5 (17.3 to 29.7) | 26.6 (22.1 to 31.1) | 35.8 (28.7 to 42.9) |
| Week 16: $\geq 5\%$ Change | 37.2 (32.3 to 42.2) | 36.9 (29.8 to 43.9) | 36.9 (31.9 to 41.8) | 46.6 (39.2 to 54) |
| Week 16: $\geq 10\%$ Change | 25.5 (21.1 to 30) | 25.1 (18.8 to 31.5) | 26.3 (21.8 to 30.8) | 28.4 (21.7 to 35.1) |
| Week 24: $\geq 5\%$ Change | 35.6 (30.7 to 40.5) | 38 (30.9 to 45.1) | 33.6 (28.8 to 38.4) | 42.6 (35.3 to 49.9) |
| Week 24: $\geq 10\%$ Change | 24.5 (20.1 to 28.8) | 21.8 (15.7 to 27.8) | 22.5 (18.2 to 26.8) | 32.4 (25.5 to 39.3) |
| Week 36: $\geq 5\%$ Change | 35.3 (30.4 to 40.2) | 32.4 (25.5 to 39.3) | 31.7 (27 to 36.5) | 38.6 (31.4 to 45.8) |
| Week 36: $\geq 10\%$ Change | 23.4 (19 to 27.7) | 22.9 (16.7 to 29.1) | 22.2 (18 to 26.5) | 27.3 (20.7 to 33.9) |
| Week 48: $\geq 5\%$ Change | 30.2 (25.5 to 34.9) | 32.4 (25.5 to 39.3) | 30.9 (26.2 to 35.6) | 36.4 (29.3 to 43.5) |
| Week 48: $\geq 10\%$ Change | 21.7 (17.5 to 26) | 21.8 (15.7 to 27.8) | 21.4 (17.2 to 25.6) | 19.9 (14 to 25.8) |
| Week 60: $\geq 5\%$ Change | 30.4 (25.7 to 35.1) | 32.4 (25.5 to 39.3) | 29.3 (24.6 to 33.9) | 38.6 (31.4 to 45.8) |

| | | | | |
|-----------------------------|---------------------|---------------------|---------------------|---------------------|
| Week 60: $\geq 10\%$ Change | 20.4 (16.3 to 24.5) | 25.1 (18.8 to 31.5) | 19.2 (15.2 to 23.3) | 24.4 (18.1 to 30.8) |
| Week 72: $\geq 5\%$ Change | 29.3 (24.7 to 34) | 34.6 (27.7 to 41.6) | 25.5 (21 to 29.9) | 33 (26 to 39.9) |
| Week 72: $\geq 10\%$ Change | 18.2 (14.3 to 22.1) | 22.3 (16.2 to 28.4) | 18.2 (14.2 to 22.1) | 23.3 (17.1 to 29.5) |
| Week 84: $\geq 5\%$ Change | 23.1 (18.8 to 27.4) | 28.5 (21.9 to 35.1) | 23.3 (19 to 27.6) | 26.1 (19.6 to 32.6) |
| Week 84: $\geq 10\%$ Change | 14.9 (11.3 to 18.6) | 21.2 (15.2 to 27.2) | 15.7 (12 to 19.4) | 19.9 (14 to 25.8) |
| Week 96: $\geq 5\%$ Change | 15.5 (11.8 to 19.2) | 14.5 (9.4 to 19.7) | 13.8 (10.3 to 17.3) | 15.3 (10 to 20.7) |
| Week 96: $\geq 10\%$ Change | 8.7 (5.8 to 11.6) | 10.1 (5.7 to 14.5) | 10.3 (7.2 to 13.4) | 9.1 (4.8 to 13.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Part B Treatment Cohort: Percentage of Subjects With Response Based on Relative Change in Percent Predicted FEV1 From Baseline

| | |
|-----------------|--|
| End point title | Part B Treatment Cohort: Percentage of Subjects With Response Based on Relative Change in Percent Predicted FEV1 From Baseline |
|-----------------|--|

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration. Hankinson and Wang standards were used to calculate percent predicted FEV1 (for age, gender, race, and height). Percentage of subjects with at least 5% relative change in percent predicted FEV1 from Baseline were reported. FAS (Study 102) was used for Arm 6 and 7, and included all subjects randomized in the cohort 4 of study 102 and dosed. Analysis was performed using baseline of the previous study VX09-809-102 (2010-020413-90) for Arm 6 and 7.

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

End point timeframe:

Baseline (Study 102); Day 15, Week 8, 16, 24, 36, 48, 60, 72, 84, 96 (Study 105)

| End point values | Arm 6: Part B - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 7: Part B - Placebo- LUM 400 mg q12h/ IVA 250 mg q12h | | |
|----------------------------------|--|---|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 62 | 63 | | |
| Units: Percentage of Subjects | | | | |
| number (confidence interval 95%) | | | | |
| Day 15: $\geq 5\%$ Change | 21 (10.8 to 31.1) | 12.7 (4.5 to 20.9) | | |
| Week 8: $\geq 5\%$ Change | 11.3 (3.4 to 19.2) | 19 (9.4 to 28.7) | | |
| Week 16: $\geq 5\%$ Change | 19.4 (9.5 to 29.2) | 15.9 (6.8 to 24.9) | | |
| Week 24: $\geq 5\%$ Change | 12.9 (4.6 to 21.2) | 12.7 (4.5 to 20.9) | | |

| | | | | |
|----------------------------|-------------------|-------------------|--|--|
| Week 36: $\geq 5\%$ Change | 6.5 (0.3 to 12.6) | 6.3 (0.3 to 12.4) | | |
| Week 48: $\geq 5\%$ Change | 6.5 (0.3 to 12.6) | 4.8 (0 to 10) | | |
| Week 60: $\geq 5\%$ Change | 6.5 (0.3 to 12.6) | 6.3 (0.3 to 12.4) | | |
| Week 72: $\geq 5\%$ Change | 3.2 (0 to 7.6) | 0 (0 to 0) | | |
| Week 84: $\geq 5\%$ Change | 1.6 (0 to 4.7) | 1.6 (0 to 4.7) | | |
| Week 96: $\geq 5\%$ Change | 0 (0 to 0) | 0 (0 to 0) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Part A Observation Cohort: Number of Subjects With Serious Adverse Events (SAEs)

| | |
|-----------------|--|
| End point title | Part A Observation Cohort: Number of Subjects With Serious Adverse Events (SAEs) ^[16] |
|-----------------|--|

End point description:

AE: as any untoward medical occurrence in a subject during the study; the event does not necessarily have a causal relationship with the treatment. This includes any newly occurring event or previous condition that has increased in severity or frequency after the informed consent form is signed. AE includes serious as well as non-serious AEs. SAE (subset of AE): medical event or condition, which falls into any of the following categories, regardless of its relationship to the study drug: death, life threatening adverse experience, In-patient hospitalization/prolongation of hospitalization, persistent/significant disability or incapacity, congenital anomaly/birth defect, important medical event. Safety Set (study 105) included all subjects who were enrolled in Part A Observation Cohort.

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

End point timeframe:

up to 2 years

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only arms which are applicable to the endpoint are reported.

| | | | | |
|-----------------------------|------------------------------------|--|--|--|
| End point values | Arm 5: Part A Observational Cohort | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 19 | | | |
| Units: subjects | | | | |
| number (not applicable) | 7 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 up to Week 105

Adverse event reporting additional description:

Non-SAEs were not collected for Arm 5: Part A Observational Cohort. Only SAEs were collected.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 19.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Arm 1: Part A LUM 600 mg qd/ IVA 250 mg q12h |
|-----------------------|--|

Reporting group description:

Subjects who received LUM 600 mg qd in fixed dose combination with IVA 250 mg in the previous study VX12-809-103 (2012-003989-40) and VX12-809-104 (2012-003990-24), received the same treatment in this study 105 (2013-000604-41) up to Week 96.

| | |
|-----------------------|---|
| Reporting group title | Arm 2: Part A PlaceboLUM 600 mg qd/ IVA 250 mg q12h |
|-----------------------|---|

Reporting group description:

Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h in this study 105 (2013-000604-41) up to Week 96.

| | |
|-----------------------|--|
| Reporting group title | Arm 3: Part A LUM 400 mg q12h/ IVA 250 mg q12h |
|-----------------------|--|

Reporting group description:

Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received the same treatment in this study VX12-809-105 (2013-000604-41) up to Week 96.

| | |
|-----------------------|--|
| Reporting group title | Arm 4: Part A - Placebo - LUM 400 mg q12h/ IVA 250 mg q12h |
|-----------------------|--|

Reporting group description:

Subjects who received placebo matched to LUM and IVA in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study 105 (2013-000604-41) up to Week 96.

| | |
|-----------------------|------------------------------------|
| Reporting group title | Arm 5: Part A Observational Cohort |
|-----------------------|------------------------------------|

Reporting group description:

Subjects who received either LUM 600 mg qd in fixed dose combination with IVA 250 mg q12h or LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h or placebo matched to LUM and IVA q12h in the previous study VX12-809-103 (2012-003989-40) or VX12-809-104 (2012-003990-24), were observed (did not receive study drug) in this study VX12-809-105 (2013-000604-41) for up to 2 years.

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| Reporting group title | Arm 6: Part B LUM 400 mg q12h/ IVA 250 mg q12h |
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Reporting group description:

Subjects who received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received the same treatment in this VX12-809-105 (2013-000604-41) up to Week 96.

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|-----------------------|--|
| Reporting group title | Arm 7: Part B - Placebo - LUM 400 mg q12h/ IVA 250 mg q12h |
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Reporting group description:

Subjects who received placebo matched to LUM and IVA tablet in Cohort 4 of the previous study VX09-809-102 (2010-020413-90), received LUM 400 mg q12h in fixed dose combination with IVA 250 mg q12h in this study VX12-809-105 (2013-000604-41) up to Week 96.

| Serious adverse events | Arm 1: Part A LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A PlaceboLUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A LUM 400 mg q12h/ IVA 250 mg q12h |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 156 / 335 (46.57%) | 77 / 178 (43.26%) | 143 / 340 (42.06%) |
| number of deaths (all causes) | 0 | 1 | 2 |
| number of deaths resulting from adverse events | | | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertensive crisis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |

| | | | |
|---|------------------|-----------------|------------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Medical device site thrombosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Serum sickness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Type IV hypersensitivity reaction | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Haemoptysis | | | |
| subjects affected / exposed | 17 / 335 (5.07%) | 7 / 178 (3.93%) | 10 / 340 (2.94%) |
| occurrences causally related to treatment / all | 1 / 24 | 1 / 7 | 0 / 16 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 1 | 0 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Respiration abnormal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atelectasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nasal polyps | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiectasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract congestion | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary bulla | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adjustment disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Major depression | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicide attempt | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Pulmonary function test decreased | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial test positive | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Forced expiratory volume decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver function test increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza A virus test positive | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ligament rupture | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial bones fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| Cystic fibrosis related diabetes | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Cystic fibrosis pancreatic subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Bradycardia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Dizziness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Juvenile myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lumbar radiculopathy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neurological symptom | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Deafness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Eye disorders | | | |
| Cataract subcapsular | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Distal intestinal obstruction syndrome | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 6 / 340 (1.76%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 1 / 8 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Gastritis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal angiodysplasia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mechanical ileus | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyarthritis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Infective pulmonary exacerbation of cystic fibrosis | | | |

| | | | |
|---|--------------------|-------------------|--------------------|
| subjects affected / exposed | 113 / 335 (33.73%) | 61 / 178 (34.27%) | 111 / 340 (32.65%) |
| occurrences causally related to treatment / all | 8 / 219 | 2 / 130 | 4 / 212 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 4 / 178 (2.25%) | 5 / 340 (1.47%) |
| occurrences causally related to treatment / all | 0 / 7 | 3 / 6 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 6 / 340 (1.76%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopulmonary aspergillosis allergic | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Device related infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Device related sepsis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tracheobronchitis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic sinusitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis E | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infective exacerbation of bronchiectasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection pseudomonal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mediastinitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mycobacterium abscessus infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parotitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Periorbital abscess | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonsillar abscess | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia pseudomonal | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral upper respiratory tract infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kidney infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Arm 4: Part A - Placebo - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 5: Part A Observational Cohort | Arm 6: Part B LUM 400 mg q12h/ IVA 250 mg q12h |
|---|---|---------------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 89 / 176 (50.57%) | 7 / 19 (36.84%) | 18 / 55 (32.73%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |

| | | | |
|--|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertensive crisis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Medical device site thrombosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Serum sickness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Type IV hypersensitivity reaction | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Haemoptysis | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 1 / 19 (5.26%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 3 / 9 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiration abnormal | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences causally related to treatment / all | 3 / 3 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Nasal polyps | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiectasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleuritic pain | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary bulla | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anxiety | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adjustment disorder | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adjustment disorder with depressed mood | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Major depression | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 1 / 19 (5.26%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicide attempt | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Pulmonary function test decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Forced expiratory volume decreased | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences causally related to treatment / all | 2 / 4 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver function test increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial bones fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Congenital, familial and genetic disorders | | | |
| Cystic fibrosis related diabetes | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cystic fibrosis pancreatic | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Bradycardia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Cardiac arrest | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 1 / 19 (5.26%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Juvenile myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lumbar radiculopathy | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neurological symptom | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Deafness | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Cataract subcapsular | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Distal intestinal obstruction syndrome | | | |

| | | | |
|---|------------------|----------------|----------------|
| subjects affected / exposed | 10 / 176 (5.68%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 10 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal reflux disease | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal angiodysplasia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mechanical ileus | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary colic | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-------------------|-----------------|------------------|
| Renal colic | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyarthritis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Infective pulmonary exacerbation of cystic fibrosis | | | |
| subjects affected / exposed | 59 / 176 (33.52%) | 5 / 19 (26.32%) | 15 / 55 (27.27%) |
| occurrences causally related to treatment / all | 5 / 107 | 0 / 11 | 2 / 20 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 1 / 19 (5.26%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopulmonary aspergillosis allergic | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Device related infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Device related sepsis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis E | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infective exacerbation of bronchiectasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 1 / 19 (5.26%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection pseudomonal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mediastinitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mycobacterium abscessus infection | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parotitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Periorbital abscess | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonsillar abscess | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural infection | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal sepsis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kidney infection | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|--|--|
| Serious adverse events | Arm 7: Part B - Placebo - LUM 400 mg q12h/ IVA 250 mg q12h | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 21 / 60 (35.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | | | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertensive crisis | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Medical device site thrombosis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Serum sickness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Type IV hypersensitivity reaction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Haemoptysis | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences causally related to treatment / all | 1 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiration abnormal | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nasal polyps | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Acute respiratory failure | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Asthma | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchiectasis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dyspnoea | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoxia | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract congestion | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleuritic pain | | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary bulla | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Depression | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Adjustment disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Adjustment disorder with depressed mood | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Major depression | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Suicide attempt | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |
| Pulmonary function test decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bacterial test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Forced expiratory volume decreased | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Liver function test increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Foot fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|----------------|--|--|
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pelvic fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Facial bones fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Congenital, familial and genetic disorders | | | |
| Cystic fibrosis related diabetes | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cystic fibrosis pancreatic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Bradycardia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|----------------|--|--|
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myocardial ischaemia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Juvenile myoclonic epilepsy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lumbar radiculopathy | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neurological symptom | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vocal cord paralysis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear and labyrinth disorders | | | |
| Deafness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Cataract subcapsular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Distal intestinal obstruction syndrome | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Small intestinal obstruction | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abdominal pain | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abdominal pain upper | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Constipation | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diarrhoea | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal obstruction | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastritis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrooesophageal reflux disease | | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abdominal wall haematoma | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Faecaloma | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Food poisoning | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal angiodysplasia | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hiatus hernia | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Inguinal hernia | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mechanical ileus | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis | | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Biliary colic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|------------------|--|--|
| Renal colic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nephrotic syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Polyarthritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Infective pulmonary exacerbation of cystic fibrosis | | | |
| subjects affected / exposed | 15 / 60 (25.00%) | | |
| occurrences causally related to treatment / all | 2 / 22 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Appendicitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchopulmonary aspergillosis allergic | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Acute sinusitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Device related infection | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Device related sepsis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis | | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory tract infection bacterial | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tracheobronchitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Anal abscess | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacteraemia | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Chronic sinusitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis viral | | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatitis E | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infection | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infective exacerbation of bronchiectasis | | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract infection bacterial | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lung infection | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lung infection pseudomonal | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mediastinitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mycobacterium abscessus infection | | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nasopharyngitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Parotitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Periorbital abscess | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peritonitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peritonsillar abscess | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia bacterial | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia pseudomonal | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural infection | | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelonephritis acute | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory syncytial virus infection | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rhinovirus infection | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinusitis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Staphylococcal sepsis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tooth abscess | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Viral upper respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Kidney infection | | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Diabetic ketoacidosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Arm 1: Part A LUM 600 mg qd/ IVA 250 mg q12h | Arm 2: Part A PlaceboLUM 600 mg qd/ IVA 250 mg q12h | Arm 3: Part A LUM 400 mg q12h/ IVA 250 mg q12h |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 328 / 335 (97.91%) | 177 / 178 (99.44%) | 332 / 340 (97.65%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign breast neoplasm | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melanocytic naevus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|----------------------|----------------------|----------------------|
| Basal cell carcinoma subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Lipoma subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Malignant melanoma subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Metastases to bone subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Neurofibroma subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Seborrhoeic keratosis subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Skin papilloma subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Uterine leiomyoma subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Vascular disorders | | | |
| Hypertension subjects affected / exposed occurrences (all) | 3 / 335 (0.90%) 3 | 2 / 178 (1.12%) 4 | 4 / 340 (1.18%) 5 |
| Deep vein thrombosis subjects affected / exposed occurrences (all) | 3 / 335 (0.90%) 4 | 1 / 178 (0.56%) 1 | 2 / 340 (0.59%) 2 |
| Hot flush subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 2 / 178 (1.12%) 2 | 1 / 340 (0.29%) 1 |
| Flushing | | | |

| | | | |
|--|-------------------|-------------------|-------------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 2 | 1 |
| Haematoma | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral coldness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vasodilatation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombophlebitis superficial | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Thrombosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Surgical and medical procedures | | | |
| Ethmoid sinus surgery | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wisdom teeth removal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 60 / 335 (17.91%) | 27 / 178 (15.17%) | 47 / 340 (13.82%) |
| occurrences (all) | 84 | 41 | 64 |
| Fatigue | | | |

| | | | |
|-----------------------------|-------------------|-------------------|-------------------|
| subjects affected / exposed | 45 / 335 (13.43%) | 26 / 178 (14.61%) | 36 / 340 (10.59%) |
| occurrences (all) | 57 | 32 | 47 |
| Pain | | | |
| subjects affected / exposed | 12 / 335 (3.58%) | 5 / 178 (2.81%) | 6 / 340 (1.76%) |
| occurrences (all) | 13 | 6 | 6 |
| Malaise | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 4 / 178 (2.25%) | 9 / 340 (2.65%) |
| occurrences (all) | 3 | 5 | 9 |
| Chest discomfort | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 6 / 178 (3.37%) | 3 / 340 (0.88%) |
| occurrences (all) | 8 | 8 | 5 |
| Chest pain | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 6 / 178 (3.37%) | 2 / 340 (0.59%) |
| occurrences (all) | 7 | 8 | 2 |
| Asthenia | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 2 / 178 (1.12%) | 5 / 340 (1.47%) |
| occurrences (all) | 8 | 2 | 5 |
| Chills | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 3 / 178 (1.69%) | 6 / 340 (1.76%) |
| occurrences (all) | 5 | 4 | 6 |
| Influenza like illness | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 2 / 178 (1.12%) | 5 / 340 (1.47%) |
| occurrences (all) | 2 | 3 | 5 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 1 | 1 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Feeling cold | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 2 | 1 |
| Application site vesicles | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Catheter site haematoma | | | |

| | | | |
|------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Catheter site pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Vessel puncture site bruise | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Application site irritation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Catheter site rash | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Drug intolerance | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Drug withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Facial pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hernia | | | |

| | | | |
|--------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hunger | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion site bruising | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Infusion site pruritus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mass | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Medical device pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Medical device site ulcer | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vaccination site pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vessel puncture site pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vessel puncture site phlebitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infusion site inflammation | | | |

| | | | |
|-----------------------------------|------------------|-----------------|------------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Local swelling | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Medical device site extravasation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 13 / 335 (3.88%) | 5 / 178 (2.81%) | 19 / 340 (5.59%) |
| occurrences (all) | 13 | 7 | 22 |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 3 / 178 (1.69%) | 4 / 340 (1.18%) |
| occurrences (all) | 6 | 3 | 4 |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Allergy to arthropod bite | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Allergy to animal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| House dust allergy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Immunisation reaction | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Mycotic allergy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|----------------------|----------------------|-----------------------|
| Reaction to food additive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Serum sickness subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Smoke sensitivity subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Social circumstances Menopause subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea subjects affected / exposed occurrences (all) | 6 / 335 (1.79%) 7 | 3 / 178 (1.69%) 3 | 8 / 340 (2.35%) 15 |
| Metrorrhagia subjects affected / exposed occurrences (all) | 6 / 335 (1.79%) 8 | 2 / 178 (1.12%) 2 | 2 / 340 (0.59%) 2 |
| Abnormal withdrawal bleeding subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Cervical polyp subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Ovarian cyst subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 2 / 340 (0.59%) 3 |
| Vaginal haemorrhage subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Menstruation irregular subjects affected / exposed occurrences (all) | 3 / 335 (0.90%) 3 | 1 / 178 (0.56%) 1 | 3 / 340 (0.88%) 3 |
| Menorrhagia | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 2 |
| Vaginal discharge | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 0 | 3 |
| Polycystic ovaries | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Endometriosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Vulvovaginal pruritus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Acquired hydrocele | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Adnexa uteri mass | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Amenorrhoea | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Balanoposthitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bartholin's cyst | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erectile dysfunction | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Ovarian cyst ruptured | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Ovarian hyperfunction | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Polymenorrhoea | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus genital | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rectocele | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Testicular cyst | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Testicular pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Uterine prolapse | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vaginal inflammation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal discomfort | | | |

| | | | |
|---|--------------------|-------------------|--------------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vulvovaginal pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 167 / 335 (49.85%) | 92 / 178 (51.69%) | 145 / 340 (42.65%) |
| occurrences (all) | 355 | 181 | 292 |
| Sputum increased | | | |
| subjects affected / exposed | 75 / 335 (22.39%) | 36 / 178 (20.22%) | 79 / 340 (23.24%) |
| occurrences (all) | 127 | 52 | 119 |
| Haemoptysis | | | |
| subjects affected / exposed | 61 / 335 (18.21%) | 37 / 178 (20.79%) | 68 / 340 (20.00%) |
| occurrences (all) | 109 | 64 | 136 |
| Dyspnoea | | | |
| subjects affected / exposed | 52 / 335 (15.52%) | 33 / 178 (18.54%) | 53 / 340 (15.59%) |
| occurrences (all) | 65 | 38 | 71 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 45 / 335 (13.43%) | 21 / 178 (11.80%) | 44 / 340 (12.94%) |
| occurrences (all) | 57 | 24 | 66 |
| Respiration abnormal | | | |
| subjects affected / exposed | 39 / 335 (11.64%) | 30 / 178 (16.85%) | 34 / 340 (10.00%) |
| occurrences (all) | 50 | 42 | 43 |
| Nasal congestion | | | |
| subjects affected / exposed | 40 / 335 (11.94%) | 20 / 178 (11.24%) | 37 / 340 (10.88%) |
| occurrences (all) | 59 | 27 | 59 |
| Productive cough | | | |
| subjects affected / exposed | 20 / 335 (5.97%) | 10 / 178 (5.62%) | 21 / 340 (6.18%) |
| occurrences (all) | 30 | 13 | 30 |
| Sinus congestion | | | |
| subjects affected / exposed | 22 / 335 (6.57%) | 9 / 178 (5.06%) | 18 / 340 (5.29%) |
| occurrences (all) | 26 | 14 | 19 |
| Rhinorrhoea | | | |

| | | | |
|------------------------------------|------------------|------------------|------------------|
| subjects affected / exposed | 26 / 335 (7.76%) | 8 / 178 (4.49%) | 12 / 340 (3.53%) |
| occurrences (all) | 30 | 10 | 14 |
| Wheezing | | | |
| subjects affected / exposed | 16 / 335 (4.78%) | 7 / 178 (3.93%) | 13 / 340 (3.82%) |
| occurrences (all) | 20 | 9 | 18 |
| Paranasal sinus hypersecretion | | | |
| subjects affected / exposed | 14 / 335 (4.18%) | 4 / 178 (2.25%) | 18 / 340 (5.29%) |
| occurrences (all) | 17 | 4 | 25 |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 19 / 335 (5.67%) | 5 / 178 (2.81%) | 14 / 340 (4.12%) |
| occurrences (all) | 19 | 5 | 20 |
| Asthma | | | |
| subjects affected / exposed | 13 / 335 (3.88%) | 6 / 178 (3.37%) | 16 / 340 (4.71%) |
| occurrences (all) | 15 | 6 | 22 |
| Lower respiratory tract congestion | | | |
| subjects affected / exposed | 20 / 335 (5.97%) | 3 / 178 (1.69%) | 12 / 340 (3.53%) |
| occurrences (all) | 21 | 3 | 15 |
| Rales | | | |
| subjects affected / exposed | 10 / 335 (2.99%) | 9 / 178 (5.06%) | 10 / 340 (2.94%) |
| occurrences (all) | 10 | 10 | 10 |
| Sputum discoloured | | | |
| subjects affected / exposed | 13 / 335 (3.88%) | 4 / 178 (2.25%) | 12 / 340 (3.53%) |
| occurrences (all) | 14 | 4 | 13 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 9 / 335 (2.69%) | 2 / 178 (1.12%) | 12 / 340 (3.53%) |
| occurrences (all) | 9 | 2 | 16 |
| Dysphonia | | | |
| subjects affected / exposed | 10 / 335 (2.99%) | 2 / 178 (1.12%) | 10 / 340 (2.94%) |
| occurrences (all) | 13 | 2 | 12 |
| Bronchospasm | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 4 / 178 (2.25%) | 8 / 340 (2.35%) |
| occurrences (all) | 9 | 5 | 12 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 9 / 335 (2.69%) | 10 / 178 (5.62%) | 7 / 340 (2.06%) |
| occurrences (all) | 10 | 10 | 7 |
| Epistaxis | | | |

| | | | |
|--|------------------|-----------------|------------------|
| subjects affected / exposed | 10 / 335 (2.99%) | 2 / 178 (1.12%) | 10 / 340 (2.94%) |
| occurrences (all) | 13 | 2 | 10 |
| Nasal polyps | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 3 / 178 (1.69%) | 8 / 340 (2.35%) |
| occurrences (all) | 5 | 3 | 9 |
| Pleuritic pain | | | |
| subjects affected / exposed | 10 / 335 (2.99%) | 5 / 178 (2.81%) | 4 / 340 (1.18%) |
| occurrences (all) | 11 | 5 | 4 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 8 / 335 (2.39%) | 4 / 178 (2.25%) | 6 / 340 (1.76%) |
| occurrences (all) | 9 | 5 | 7 |
| Increased viscosity of bronchial secretion | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 6 / 178 (3.37%) | 4 / 340 (1.18%) |
| occurrences (all) | 9 | 7 | 4 |
| Upper respiratory tract congestion | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 5 / 340 (1.47%) |
| occurrences (all) | 2 | 2 | 5 |
| Increased bronchial secretion | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 5 | 1 | 3 |
| Painful respiration | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 5 / 340 (1.47%) |
| occurrences (all) | 2 | 1 | 5 |
| Throat irritation | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 0 / 178 (0.00%) | 5 / 340 (1.47%) |
| occurrences (all) | 4 | 0 | 5 |
| Nasal discharge discolouration | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 4 / 340 (1.18%) |
| occurrences (all) | 2 | 1 | 5 |
| Bronchiectasis | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 2 | 1 |
| Hypoxia | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| Paranasal sinus discomfort subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 2 / 178 (1.12%) 2 | 3 / 340 (0.88%) 3 |
| Bronchial hyperreactivity subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 1 / 178 (0.56%) 1 | 3 / 340 (0.88%) 3 |
| Lung infiltration subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Nocturnal dyspnoea subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Obstructive airways disorder subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Oropharyngeal discomfort subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Rhinalgia subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Bronchial obstruction subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Bronchial secretion retention subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 2 / 178 (1.12%) 2 | 1 / 340 (0.29%) 1 |
| Increased upper airway secretion subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 2 / 340 (0.59%) 2 |
| Sneezing subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 3 | 0 / 178 (0.00%) 0 | 3 / 340 (0.88%) 3 |
| Nasal oedema subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 3 / 340 (0.88%) 3 |

| | | | |
|--------------------------------------|-----------------|-----------------|-----------------|
| Nasal mucosal disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 2 | 3 |
| Pleurisy | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 1 | 1 |
| Pulmonary pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Sinus disorder | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 1 | 1 |
| Sputum retention | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 1 | 3 |
| Nasal dryness | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Nasal inflammation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 1 |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Allergic sinusitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|------------------------------------|-----------------|-----------------|-----------------|
| Lung disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Nasal septum deviation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Rhonchi | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Sinus polyp | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Acquired diaphragmatic eventration | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Allergic respiratory disease | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Allergic respiratory symptom | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchial irritation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchostenosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Hyperventilation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypopnoea | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased viscosity of upper respiratory secretion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lung consolidation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung hyperinflation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasal turbinate hypertrophy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Orthopnoea | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Paranasal cyst | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngeal oedema | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pleural fibrosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumomediastinum | | | |

| | | | |
|---------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary bulla | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reflux laryngitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract haemorrhage | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory tract inflammation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract irritation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Throat tightness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillolith | | | |

| | | | |
|---|------------------------|-----------------------|-----------------------|
| subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Tracheal disorder subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Tracheal inflammation subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 2 |
| Psychiatric disorders | | | |
| Anxiety subjects affected / exposed occurrences (all) | 14 / 335 (4.18%) 16 | 5 / 178 (2.81%) 5 | 9 / 340 (2.65%) 9 |
| Insomnia subjects affected / exposed occurrences (all) | 7 / 335 (2.09%) 7 | 9 / 178 (5.06%) 12 | 9 / 340 (2.65%) 10 |
| Depressed mood subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 3 / 340 (0.88%) 3 |
| Panic attack subjects affected / exposed occurrences (all) | 4 / 335 (1.19%) 4 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Attention deficit/hyperactivity disorder subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Stress subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Adjustment disorder subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Adjustment disorder with anxiety subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Adjustment disorder with depressed mood | | | |

| | | | |
|---------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Agitation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Decreased interest | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Disturbance in social behaviour | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Encopresis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Food aversion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hallucination, visual | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Intentional self-injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Listless | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervousness | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Obsessive-compulsive disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sleep disorder | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Somnambulism subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Suicidal ideation subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Depression subjects affected / exposed occurrences (all) | 7 / 335 (2.09%) 7 | 4 / 178 (2.25%) 4 | 8 / 340 (2.35%) 8 |
| Product issues | | | |
| Device dislocation subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Device occlusion subjects affected / exposed occurrences (all) | 4 / 335 (1.19%) 4 | 1 / 178 (0.56%) 1 | 2 / 340 (0.59%) 2 |
| Device leakage subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Hepatobiliary disorders | | | |
| Cholecystitis subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Jaundice subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Cholelithiasis subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 2 / 178 (1.12%) 2 | 0 / 340 (0.00%) 0 |
| Biliary colic subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 3 / 340 (0.88%) 3 |
| Hepatomegaly | | | |

| | | | |
|---|-------------------------|-------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 2 / 340 (0.59%) 3 |
| Cholecystitis chronic subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Hepatic pain subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 2 |
| Hepatic steatosis subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Investigations | | | |
| Pulmonary function test decreased subjects affected / exposed occurrences (all) | 35 / 335 (10.45%) 42 | 23 / 178 (12.92%) 28 | 29 / 340 (8.53%) 35 |
| Blood creatine phosphokinase increased subjects affected / exposed occurrences (all) | 26 / 335 (7.76%) 33 | 23 / 178 (12.92%) 29 | 23 / 340 (6.76%) 38 |
| Forced expiratory volume decreased subjects affected / exposed occurrences (all) | 26 / 335 (7.76%) 31 | 12 / 178 (6.74%) 13 | 28 / 340 (8.24%) 31 |
| Bacterial test positive subjects affected / exposed occurrences (all) | 29 / 335 (8.66%) 42 | 7 / 178 (3.93%) 9 | 30 / 340 (8.82%) 42 |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 10 / 335 (2.99%) 12 | 14 / 178 (7.87%) 15 | 14 / 340 (4.12%) 18 |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 12 / 335 (3.58%) 13 | 13 / 178 (7.30%) 14 | 15 / 340 (4.41%) 20 |
| Blood glucose decreased subjects affected / exposed occurrences (all) | 4 / 335 (1.19%) 4 | 1 / 178 (0.56%) 1 | 4 / 340 (1.18%) 4 |
| Blood alkaline phosphatase increased | | | |

| | | | |
|--------------------------------------|------------------|-----------------|------------------|
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 2 | 1 | 6 |
| Weight decreased | | | |
| subjects affected / exposed | 16 / 335 (4.78%) | 7 / 178 (3.93%) | 18 / 340 (5.29%) |
| occurrences (all) | 16 | 7 | 20 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 6 / 178 (3.37%) | 3 / 340 (0.88%) |
| occurrences (all) | 8 | 8 | 3 |
| Blood glucose increased | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 7 / 178 (3.93%) | 2 / 340 (0.59%) |
| occurrences (all) | 5 | 7 | 2 |
| Fungal test positive | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 4 / 178 (2.25%) | 6 / 340 (1.76%) |
| occurrences (all) | 6 | 7 | 8 |
| Vitamin D decreased | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 3 / 178 (1.69%) | 3 / 340 (0.88%) |
| occurrences (all) | 6 | 3 | 3 |
| Liver function test increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 6 / 178 (3.37%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 8 | 3 |
| White blood cell count increased | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 5 / 178 (2.81%) | 2 / 340 (0.59%) |
| occurrences (all) | 4 | 5 | 2 |
| Atypical mycobacterium test positive | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 5 / 178 (2.81%) | 2 / 340 (0.59%) |
| occurrences (all) | 3 | 5 | 2 |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 3 / 178 (1.69%) | 3 / 340 (0.88%) |
| occurrences (all) | 3 | 3 | 3 |
| Neutrophil count increased | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 3 / 178 (1.69%) | 3 / 340 (0.88%) |
| occurrences (all) | 2 | 4 | 4 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 3 | 1 | 3 |

| | | | |
|--|----------------------|----------------------|----------------------|
| Blood magnesium decreased subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 2 / 178 (1.12%) 2 | 1 / 340 (0.29%) 1 |
| Clostridium test positive subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 1 / 178 (0.56%) 1 | 1 / 340 (0.29%) 1 |
| Oxygen saturation decreased subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 0 / 178 (0.00%) 0 | 2 / 340 (0.59%) 2 |
| Transaminases increased subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 2 / 178 (1.12%) 2 | 1 / 340 (0.29%) 1 |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 3 | 0 / 178 (0.00%) 0 | 2 / 340 (0.59%) 3 |
| Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 2 / 178 (1.12%) 2 | 1 / 340 (0.29%) 1 |
| Blood bicarbonate decreased subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Blood immunoglobulin E increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 1 / 340 (0.29%) 1 |
| Body temperature increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Crystal urine present subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Haemoglobin decreased subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 2 |
| Protein urine present | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Staphylococcus test positive | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 2 | 1 |
| Blood calcium increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood pressure systolic increased | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood thyroid stimulating hormone increased | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Breath sounds abnormal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Eosinophil count increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Forced vital capacity decreased | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Glucose urine present | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Glycosylated haemoglobin increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|--|----------------------|----------------------|----------------------|
| Hepatic enzyme increased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 1 / 340 (0.29%) 1 |
| Monocyte count increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 1 / 340 (0.29%) 1 |
| Pseudomonas test positive subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 1 / 340 (0.29%) 1 |
| Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 1 / 340 (0.29%) 1 |
| Blood pressure increased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 2 / 178 (1.12%) 2 | 0 / 340 (0.00%) 0 |
| Candida test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 2 / 178 (1.12%) 2 | 0 / 340 (0.00%) 0 |
| Electrocardiogram QT prolonged subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Glucose tolerance test abnormal subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Heart rate increased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 2 / 340 (0.59%) 2 |
| Human rhinovirus test positive subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 3 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Influenza B virus test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 2 / 340 (0.59%) 2 |
| International normalised ratio increased | | | |

| | | | |
|-----------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood albumin decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood immunoglobulin G increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood iron decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood potassium decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Helicobacter test positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza virus test positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Reticulocyte percentage increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sputum abnormal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Platelet count increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Respiratory syncytial virus test | | | |

| | | | |
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| positive | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aspergillus test positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood androstenedione increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood cholesterol increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood cortisol decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood creatine increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood glucose fluctuation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood magnesium increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood phosphorus decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood phosphorus increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood sodium decreased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|----------------------|----------------------|----------------------|
| Blood sodium increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Blood testosterone decreased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Blood testosterone increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 2 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Blood urine present subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Burkholderia test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Citrobacter test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Computerised tomogram thorax abnormal subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Coronavirus test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Creatinine renal clearance increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Dehydroepiandrosterone increased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Electrocardiogram PR shortened subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Electrocardiogram ST segment elevation | | | |

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| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Electrocardiogram abnormal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epstein-Barr virus antibody positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Escherichia test positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Grip strength decreased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemoglobin increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Human metapneumovirus test positive | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Human papilloma virus test positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mean cell volume increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Myoglobin blood increased | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Precancerous cells present | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Red blood cells urine positive | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
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| Reticulocyte count increased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Rubulavirus test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Ultrasound liver abnormal subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Urine analysis abnormal subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Urine bilirubin increased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Urine ketone body present subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Viral test positive subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Vitamin A decreased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Vitamin B12 decreased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Vitamin E decreased subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| White blood cell count decreased subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|-----------------------------|------------------|-----------------|-----------------|
| Contusion | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 3 / 178 (1.69%) | 8 / 340 (2.35%) |
| occurrences (all) | 7 | 3 | 9 |
| Procedural pain | | | |
| subjects affected / exposed | 10 / 335 (2.99%) | 3 / 178 (1.69%) | 8 / 340 (2.35%) |
| occurrences (all) | 12 | 3 | 9 |
| Ligament sprain | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 2 / 178 (1.12%) | 5 / 340 (1.47%) |
| occurrences (all) | 6 | 3 | 5 |
| Muscle strain | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 4 / 178 (2.25%) | 2 / 340 (0.59%) |
| occurrences (all) | 5 | 4 | 2 |
| Arthropod bite | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 3 / 178 (1.69%) | 3 / 340 (0.88%) |
| occurrences (all) | 4 | 3 | 3 |
| Laceration | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 3 / 178 (1.69%) | 5 / 340 (1.47%) |
| occurrences (all) | 2 | 3 | 5 |
| Fall | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 5 / 340 (1.47%) |
| occurrences (all) | 1 | 0 | 5 |
| Joint dislocation | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 4 | 1 | 4 |
| Joint injury | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 4 / 340 (1.18%) |
| occurrences (all) | 3 | 0 | 4 |
| Rib fracture | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 4 | 0 | 2 |
| Concussion | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 2 | 1 |
| Sunburn | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 4 | 0 | 2 |
| Periorbital haemorrhage | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post procedural swelling | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Tooth fracture | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 1 | 2 |
| Foot fracture | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 1 | 1 |
| Road traffic accident | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Chest injury | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 3 | 0 | 2 |
| Post-traumatic pain | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 0 | 2 |
| Facial bones fracture | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Back injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 1 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Hand fracture | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Ligament injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 0 | 2 |
| Sports injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Superficial injury of eye | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Animal bite | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthropod sting | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Incisional hernia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Post procedural discomfort | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 4 |
| Procedural nausea | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Stoma site discomfort | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Stoma site irritation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|--------------------------------|-----------------|-----------------|-----------------|
| Thermal burn | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Traumatic haematoma | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Wrist fracture | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Accidental exposure to product | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Animal scratch | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Ankle fracture | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Avulsion fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Confusion postoperative | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Ear injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Epicondylitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Excoriation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Face injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Forearm fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Head injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Heat stroke | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Incision site haematoma | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Limb crushing injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Lip injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscle injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|------------------------------|-----------------|-----------------|-----------------|
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nerve injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Peripheral nerve injury | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Post procedural complication | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Procedural anxiety | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Procedural headache | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Procedural vomiting | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinus barotrauma | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Soft tissue injury | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Splinter | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|--|------------------------|------------------------|----------------------|
| Stoma site erythema subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Stoma site haemorrhage subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Stoma site pain subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Stoma site ulcer subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Stress fracture subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Upper limb fracture subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Wound subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Congenital, familial and genetic disorders | | | |
| Thyroglossal cyst subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Cystic fibrosis related diabetes subjects affected / exposed occurrences (all) | 10 / 335 (2.99%) 10 | 10 / 178 (5.62%) 10 | 8 / 340 (2.35%) 8 |
| Cystic fibrosis hepatic disease subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Cystic fibrosis lung subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Dermoid cyst | | | |

| | | | |
|-------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Naevus flammeus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiac disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 0 / 178 (0.00%) | 4 / 340 (1.18%) |
| occurrences (all) | 5 | 0 | 4 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Sinus arrhythmia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Extrasystoles | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Left ventricular hypertrophy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---------------------------------|-------------------|-------------------|-------------------|
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 58 / 335 (17.31%) | 25 / 178 (14.04%) | 56 / 340 (16.47%) |
| occurrences (all) | 73 | 30 | 80 |
| Sinus headache | | | |
| subjects affected / exposed | 13 / 335 (3.88%) | 9 / 178 (5.06%) | 11 / 340 (3.24%) |
| occurrences (all) | 16 | 10 | 14 |
| Dizziness | | | |
| subjects affected / exposed | 9 / 335 (2.69%) | 7 / 178 (3.93%) | 6 / 340 (1.76%) |
| occurrences (all) | 14 | 8 | 6 |
| Migraine | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 2 / 178 (1.12%) | 5 / 340 (1.47%) |
| occurrences (all) | 9 | 2 | 5 |
| Lethargy | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 1 | 2 |
| Syncope | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 1 | 2 |
| Paraesthesia | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences (all) | 3 | 0 | 3 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences (all) | 4 | 0 | 3 |
| Anosmia | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 1 | 1 |
| Circadian rhythm sleep disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Carpal tunnel syndrome | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Migraine with aura | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Neuralgia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Sciatica | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Tension headache | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Tremor | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ageusia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Aphonia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Coordination abnormal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |

| | | | |
|--------------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypersomnia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyposmia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Intercostal neuralgia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Nerve compression | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nystagmus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Olfactory nerve disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Disturbance in attention | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 1 / 178 (0.56%) | 5 / 340 (1.47%) |
| occurrences (all) | 7 | 1 | 5 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Anaemia | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 0 | 1 |

| | | | |
|------------------------------|-----------------|-----------------|-----------------|
| Splenomegaly | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Bone marrow oedema | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemoconcentration | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Macrocytosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 6 / 178 (3.37%) | 5 / 340 (1.47%) |
| occurrences (all) | 6 | 8 | 5 |
| Tinnitus | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 6 / 178 (3.37%) | 1 / 340 (0.29%) |
| occurrences (all) | 5 | 7 | 1 |
| Vertigo | | | |

| | | | |
|-------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 2 | 3 |
| Cerumen impaction | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 3 |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Deafness unilateral | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear congestion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Ear pruritus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Middle ear effusion | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Motion sickness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ototoxicity | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tympanic membrane perforation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vestibular disorder | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear discomfort | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Eye disorders | | | |
| Blepharospasm | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 2 / 178 (1.12%) | 4 / 340 (1.18%) |
| occurrences (all) | 2 | 2 | 4 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Eye pruritus | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 2 | 1 |
| Lacrimation increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 0 | 4 |
| Eye swelling | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 1 |
| Ocular hyperaemia | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Diabetic retinopathy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Visual acuity reduced | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Eye haemorrhage | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|----------------------------------|-------------------|-------------------|-------------------|
| Eye pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Glaucoma | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Myopia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ulcerative keratitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 46 / 335 (13.73%) | 24 / 178 (13.48%) | 41 / 340 (12.06%) |
| occurrences (all) | 63 | 29 | 52 |
| Nausea | | | |
| subjects affected / exposed | 45 / 335 (13.43%) | 24 / 178 (13.48%) | 34 / 340 (10.00%) |
| occurrences (all) | 62 | 27 | 41 |
| Abdominal pain | | | |
| subjects affected / exposed | 42 / 335 (12.54%) | 20 / 178 (11.24%) | 33 / 340 (9.71%) |
| occurrences (all) | 48 | 25 | 48 |
| Constipation | | | |
| subjects affected / exposed | 28 / 335 (8.36%) | 13 / 178 (7.30%) | 24 / 340 (7.06%) |
| occurrences (all) | 35 | 14 | 26 |
| Vomiting | | | |
| subjects affected / exposed | 26 / 335 (7.76%) | 6 / 178 (3.37%) | 27 / 340 (7.94%) |
| occurrences (all) | 33 | 6 | 29 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 18 / 335 (5.37%) | 9 / 178 (5.06%) | 20 / 340 (5.88%) |
| occurrences (all) | 30 | 11 | 22 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 16 / 335 (4.78%) | 8 / 178 (4.49%) | 14 / 340 (4.12%) |
| occurrences (all) | 18 | 8 | 14 |
| Flatulence | | | |

| | | | |
|--|------------------|-----------------|------------------|
| subjects affected / exposed | 13 / 335 (3.88%) | 5 / 178 (2.81%) | 7 / 340 (2.06%) |
| occurrences (all) | 15 | 5 | 7 |
| Dyspepsia | | | |
| subjects affected / exposed | 8 / 335 (2.39%) | 5 / 178 (2.81%) | 10 / 340 (2.94%) |
| occurrences (all) | 9 | 6 | 12 |
| Abdominal distension | | | |
| subjects affected / exposed | 11 / 335 (3.28%) | 2 / 178 (1.12%) | 10 / 340 (2.94%) |
| occurrences (all) | 12 | 2 | 12 |
| Toothache | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 4 / 178 (2.25%) | 7 / 340 (2.06%) |
| occurrences (all) | 4 | 4 | 9 |
| Abdominal discomfort | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 1 / 178 (0.56%) | 5 / 340 (1.47%) |
| occurrences (all) | 5 | 1 | 5 |
| Distal intestinal obstruction syndrome | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 5 / 178 (2.81%) | 5 / 340 (1.47%) |
| occurrences (all) | 4 | 5 | 6 |
| Dental discomfort | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pancreatitis acute | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post-tussive vomiting | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 3 / 178 (1.69%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 3 | 1 |
| Gastritis | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 3 / 178 (1.69%) | 4 / 340 (1.18%) |
| occurrences (all) | 3 | 3 | 4 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 0 | 1 | 3 |
| Haemorrhoids | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 4 / 340 (1.18%) |
| occurrences (all) | 2 | 1 | 4 |
| Steatorrhoea | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 0 | 3 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 1 | 1 |
| Dysphagia | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 1 | 1 |
| Faecaloma | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 2 | 1 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Enteritis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences (all) | 0 | 0 | 3 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 2 | 1 |
| Haematochezia | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Inguinal hernia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 1 |
| Tooth impacted | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 0 | 1 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Bowel movement irregularity | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Breath odour | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Ileus | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Mouth ulceration | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Varices oesophageal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Abdominal hernia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Anal fistula | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Chronic gastritis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epigastric discomfort | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faecal volume decreased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
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| Faecal volume increased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faeces soft | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastric mucosal hypertrophy | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal motility disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival erythema | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival recession | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingivitis ulcerative | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Glossitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
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| Glossodynia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Intussusception | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Malabsorption | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Malpositioned teeth | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mucous stools | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oesophageal irritation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Oesophageal mucosal hyperplasia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Oesophageal pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
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| Oesophagitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral mucosal blistering | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral papule | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pancreatic insufficiency | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumoperitoneum | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reflux gastritis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retching | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth delamination | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
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| Umbilical hernia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 10 / 335 (2.99%) | 9 / 178 (5.06%) | 22 / 340 (6.47%) |
| occurrences (all) | 12 | 11 | 24 |
| Acne | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 3 / 178 (1.69%) | 8 / 340 (2.35%) |
| occurrences (all) | 3 | 3 | 8 |
| Pruritus | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 3 / 178 (1.69%) | 6 / 340 (1.76%) |
| occurrences (all) | 7 | 3 | 8 |
| Night sweats | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 7 / 178 (3.93%) | 4 / 340 (1.18%) |
| occurrences (all) | 6 | 9 | 4 |
| Urticaria | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 5 / 178 (2.81%) | 5 / 340 (1.47%) |
| occurrences (all) | 8 | 5 | 5 |
| Alopecia | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 3 / 178 (1.69%) | 3 / 340 (0.88%) |
| occurrences (all) | 4 | 3 | 3 |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 4 / 340 (1.18%) |
| occurrences (all) | 1 | 0 | 4 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 1 / 178 (0.56%) | 4 / 340 (1.18%) |
| occurrences (all) | 5 | 1 | 4 |
| Drug eruption | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 3 / 178 (1.69%) | 1 / 340 (0.29%) |
| occurrences (all) | 5 | 3 | 1 |
| Eczema | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 2 | 3 |
| Red man syndrome | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 3 / 178 (1.69%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 3 | 3 |
| Erythema | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 0 | 1 |
| Pruritus allergic | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 4 | 0 | 1 |
| Rash erythematous | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 4 / 178 (2.25%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 4 | 1 |
| Rash papular | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 5 / 340 (1.47%) |
| occurrences (all) | 1 | 0 | 6 |
| Dry skin | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 3 | 0 | 2 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 0 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 1 | 1 |
| Dermal cyst | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Swelling face | | | |

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| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Skin exfoliation | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 2 | 2 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand dermatitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Petechiae | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin disorder | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin mass | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin warm | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Solar dermatitis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Acne cystic | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fixed drug eruption | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypersensitivity vasculitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Keratosis pilaris | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Madarosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Onycholysis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Purpura senile | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash morbilliform | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rosacea | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Scar pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin irritation | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin wrinkling | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|----------------------|----------------------|----------------------|
| Urticarial vasculitis subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Renal and urinary disorders | | | |
| Stress urinary incontinence subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Nephrolithiasis subjects affected / exposed occurrences (all) | 3 / 335 (0.90%) 4 | 3 / 178 (1.69%) 5 | 2 / 340 (0.59%) 2 |
| Acute kidney injury subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 2 | 2 / 340 (0.59%) 2 |
| Dysuria subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Chromaturia subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Chronic kidney disease subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Nocturia subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Pollakiuria subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Calculus urinary subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Glycosuria subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Haematuria | | | |

| | | | |
|------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypernatremia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypocitraturia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Micturition urgency | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyelocaliectasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal failure | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal hypertrophy | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal tubular disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urinary retention | | | |

| | | | |
|---|------------------|------------------|------------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urine abnormality | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 1 |
| Goitre | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Growth hormone deficiency | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Androgen deficiency | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Cushing's syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 20 / 335 (5.97%) | 11 / 178 (6.18%) | 25 / 340 (7.35%) |
| occurrences (all) | 24 | 15 | 31 |
| Back pain | | | |
| subjects affected / exposed | 20 / 335 (5.97%) | 12 / 178 (6.74%) | 14 / 340 (4.12%) |
| occurrences (all) | 21 | 13 | 15 |
| Myalgia | | | |
| subjects affected / exposed | 19 / 335 (5.67%) | 7 / 178 (3.93%) | 13 / 340 (3.82%) |
| occurrences (all) | 20 | 7 | 20 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 13 / 335 (3.88%) | 9 / 178 (5.06%) | 12 / 340 (3.53%) |
| occurrences (all) | 14 | 10 | 13 |
| Musculoskeletal pain | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 8 / 335 (2.39%) | 6 / 178 (3.37%) | 5 / 340 (1.47%) |
| occurrences (all) | 12 | 6 | 5 |
| Pain in extremity | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 5 / 178 (2.81%) | 7 / 340 (2.06%) |
| occurrences (all) | 6 | 6 | 8 |
| Muscle spasms | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 2 / 178 (1.12%) | 7 / 340 (2.06%) |
| occurrences (all) | 4 | 2 | 9 |
| Arthritis | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 5 | 6 | 1 |
| Neck pain | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 5 | 1 | 1 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 2 | 1 |
| Osteopenia | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 4 | 1 | 1 |
| Tendonitis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 4 / 340 (1.18%) |
| occurrences (all) | 2 | 0 | 4 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 5 / 340 (1.47%) |
| occurrences (all) | 0 | 0 | 5 |
| Arthropathy | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 1 | 2 |
| Osteoporosis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Bursitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Costochondritis | | | |

| | | | |
|----------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Flank pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Groin pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint stiffness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Tenosynovitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Medial tibial stress syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscular weakness | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Osteochondrosis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Polyarthrititis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Spinal pain | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Temporomandibular joint syndrome | | | |

| | | | |
|---------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Exostosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Joint range of motion decreased | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Juvenile idiopathic arthritis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Muscle contracture | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Muscle tightness | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 2 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Myalgia intercostal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Plantar fasciitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Synovial cyst | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Tendon pain | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Torticollis | | | |

| | | | |
|----------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Chondropathy | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Coccydynia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intervertebral disc annular tear | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mastication disorder | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscle fatigue | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle oedema | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scoliosis | | | |

| | | | |
|---|--------------------|-------------------|--------------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendon disorder | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| Infective pulmonary exacerbation of cystic fibrosis | | | |
| subjects affected / exposed | 185 / 335 (55.22%) | 92 / 178 (51.69%) | 173 / 340 (50.88%) |
| occurrences (all) | 436 | 191 | 349 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 51 / 335 (15.22%) | 31 / 178 (17.42%) | 66 / 340 (19.41%) |
| occurrences (all) | 77 | 51 | 111 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 42 / 335 (12.54%) | 26 / 178 (14.61%) | 49 / 340 (14.41%) |
| occurrences (all) | 69 | 41 | 74 |
| Sinusitis | | | |
| subjects affected / exposed | 41 / 335 (12.24%) | 19 / 178 (10.67%) | 47 / 340 (13.82%) |
| occurrences (all) | 64 | 26 | 68 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 34 / 335 (10.15%) | 12 / 178 (6.74%) | 24 / 340 (7.06%) |
| occurrences (all) | 50 | 20 | 30 |
| Influenza | | | |
| subjects affected / exposed | 20 / 335 (5.97%) | 11 / 178 (6.18%) | 21 / 340 (6.18%) |
| occurrences (all) | 22 | 12 | 22 |
| Rhinitis | | | |
| subjects affected / exposed | 24 / 335 (7.16%) | 7 / 178 (3.93%) | 21 / 340 (6.18%) |
| occurrences (all) | 36 | 9 | 29 |
| Upper respiratory tract infection bacterial | | | |
| subjects affected / exposed | 16 / 335 (4.78%) | 14 / 178 (7.87%) | 18 / 340 (5.29%) |
| occurrences (all) | 17 | 19 | 28 |
| Bronchitis | | | |
| subjects affected / exposed | 15 / 335 (4.48%) | 8 / 178 (4.49%) | 12 / 340 (3.53%) |
| occurrences (all) | 32 | 12 | 19 |
| Oral candidiasis | | | |

| | | | |
|---|------------------|-----------------|------------------|
| subjects affected / exposed | 21 / 335 (6.27%) | 4 / 178 (2.25%) | 7 / 340 (2.06%) |
| occurrences (all) | 29 | 4 | 8 |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 13 / 335 (3.88%) | 4 / 178 (2.25%) | 14 / 340 (4.12%) |
| occurrences (all) | 15 | 5 | 16 |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 11 / 335 (3.28%) | 4 / 178 (2.25%) | 11 / 340 (3.24%) |
| occurrences (all) | 11 | 5 | 16 |
| Pharyngitis | | | |
| subjects affected / exposed | 10 / 335 (2.99%) | 3 / 178 (1.69%) | 5 / 340 (1.47%) |
| occurrences (all) | 11 | 3 | 9 |
| Urinary tract infection | | | |
| subjects affected / exposed | 8 / 335 (2.39%) | 6 / 178 (3.37%) | 7 / 340 (2.06%) |
| occurrences (all) | 10 | 7 | 10 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 6 / 178 (3.37%) | 7 / 340 (2.06%) |
| occurrences (all) | 7 | 10 | 17 |
| Gastroenteritis | | | |
| subjects affected / exposed | 8 / 335 (2.39%) | 2 / 178 (1.12%) | 7 / 340 (2.06%) |
| occurrences (all) | 8 | 2 | 8 |
| Bronchopulmonary aspergillosis allergic | | | |
| subjects affected / exposed | 9 / 335 (2.69%) | 6 / 178 (3.37%) | 4 / 340 (1.18%) |
| occurrences (all) | 9 | 9 | 5 |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 4 / 178 (2.25%) | 6 / 340 (1.76%) |
| occurrences (all) | 5 | 4 | 7 |
| Otitis media | | | |
| subjects affected / exposed | 9 / 335 (2.69%) | 1 / 178 (0.56%) | 8 / 340 (2.35%) |
| occurrences (all) | 11 | 1 | 9 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 12 / 335 (3.58%) | 2 / 178 (1.12%) | 4 / 340 (1.18%) |
| occurrences (all) | 16 | 2 | 4 |
| Lung infection pseudomonal | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 3 / 178 (1.69%) | 6 / 340 (1.76%) |
| occurrences (all) | 6 | 3 | 6 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Acute sinusitis | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 1 / 178 (0.56%) | 5 / 340 (1.47%) |
| occurrences (all) | 5 | 1 | 7 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 4 / 178 (2.25%) | 5 / 340 (1.47%) |
| occurrences (all) | 5 | 4 | 6 |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 9 / 335 (2.69%) | 2 / 178 (1.12%) | 2 / 340 (0.59%) |
| occurrences (all) | 12 | 3 | 3 |
| Tonsillitis | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 1 / 178 (0.56%) | 5 / 340 (1.47%) |
| occurrences (all) | 10 | 1 | 8 |
| Conjunctivitis | | | |
| subjects affected / exposed | 6 / 335 (1.79%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 6 | 1 | 2 |
| Viral infection | | | |
| subjects affected / exposed | 5 / 335 (1.49%) | 2 / 178 (1.12%) | 5 / 340 (1.47%) |
| occurrences (all) | 7 | 2 | 5 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 7 / 335 (2.09%) | 1 / 178 (0.56%) | 4 / 340 (1.18%) |
| occurrences (all) | 10 | 2 | 4 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 1 / 178 (0.56%) | 5 / 340 (1.47%) |
| occurrences (all) | 4 | 1 | 5 |
| Bacterial disease carrier | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 0 / 178 (0.00%) | 5 / 340 (1.47%) |
| occurrences (all) | 3 | 0 | 5 |
| Laryngitis | | | |
| subjects affected / exposed | 4 / 335 (1.19%) | 2 / 178 (1.12%) | 2 / 340 (0.59%) |
| occurrences (all) | 4 | 2 | 2 |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 4 / 178 (2.25%) | 3 / 340 (0.88%) |
| occurrences (all) | 2 | 4 | 4 |
| Lower respiratory tract infection bacterial | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 4 / 335 (1.19%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 5 | 1 | 3 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 3 / 340 (0.88%) |
| occurrences (all) | 1 | 2 | 3 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 4 / 340 (1.18%) |
| occurrences (all) | 0 | 1 | 4 |
| Ear infection | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 3 / 340 (0.88%) |
| occurrences (all) | 2 | 1 | 3 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 2 / 178 (1.12%) | 1 / 340 (0.29%) |
| occurrences (all) | 4 | 2 | 1 |
| Oral herpes | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 0 | 2 |
| Folliculitis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 0 | 2 |
| Lung infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 4 / 340 (1.18%) |
| occurrences (all) | 1 | 0 | 4 |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Kidney infection | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Onychomycosis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 2 | 0 | 1 |
| Tooth abscess | | | |
| subjects affected / exposed | 3 / 335 (0.90%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Bronchopulmonary aspergillosis | | | |

| | | | |
|-------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 2 | 1 |
| Eye infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Fungal skin infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Genital candidiasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Herpes dermatitis | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 3 | 0 | 1 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 0 | 0 | 2 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 3 / 340 (0.88%) |
| occurrences (all) | 0 | 0 | 3 |
| Otitis externa | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Sinusitis bacterial | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Stoma site infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Tinea infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 2 |
| Bronchitis bacterial | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Conjunctivitis bacterial | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mycobacterial disease carrier | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Superinfection bacterial | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Gastrointestinal viral infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infective exacerbation of bronchiectasis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Mycobacterium abscessus infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngitis fungal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Otitis externa fungal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Parotitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vaginal infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 2 / 178 (1.12%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Varicella | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wound infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Acne pustular | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Adenoiditis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Angular cheilitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Arthritis infective | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Atypical mycobacterial lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atypical mycobacterial pneumonia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Bacterial vaginosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchitis fungal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis viral | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epididymitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema infectiosum | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Fungal infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Furuncle | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital herpes | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Genital herpes simplex | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Genital infection fungal | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Groin abscess | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemophilus infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Helicobacter infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatitis C | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Implant site infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 2 |
| Labyrinthitis | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Localised infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral bacterial infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Overgrowth bacterial | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Overgrowth fungal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Papilloma viral infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Post procedural infection | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pseudomonas bronchitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Salpingo-oophoritis | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract infection fungal | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin bacterial infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Small intestinal bacterial overgrowth | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sputum purulent | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tracheobronchitis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Trichomoniasis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory fungal infection | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Urinary tract infection enterococcal | | | |

| | | | |
|--|------------------------|----------------------|------------------------|
| subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Vaginitis bacterial subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |
| Vulvovaginitis subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 1 / 340 (0.29%) 1 |
| Metabolism and nutrition disorders | | | |
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 11 / 335 (3.28%) 11 | 5 / 178 (2.81%) 5 | 16 / 340 (4.71%) 17 |
| Decreased appetite subjects affected / exposed occurrences (all) | 12 / 335 (3.58%) 12 | 8 / 178 (4.49%) 9 | 6 / 340 (1.76%) 7 |
| Hypoglycaemia subjects affected / exposed occurrences (all) | 5 / 335 (1.49%) 5 | 7 / 178 (3.93%) 7 | 3 / 340 (0.88%) 3 |
| Hyperglycaemia subjects affected / exposed occurrences (all) | 7 / 335 (2.09%) 8 | 4 / 178 (2.25%) 4 | 3 / 340 (0.88%) 3 |
| Iron deficiency subjects affected / exposed occurrences (all) | 6 / 335 (1.79%) 6 | 1 / 178 (0.56%) 1 | 3 / 340 (0.88%) 3 |
| Glucose tolerance impaired subjects affected / exposed occurrences (all) | 3 / 335 (0.90%) 3 | 1 / 178 (0.56%) 1 | 2 / 340 (0.59%) 2 |
| Dehydration subjects affected / exposed occurrences (all) | 1 / 335 (0.30%) 1 | 1 / 178 (0.56%) 1 | 3 / 340 (0.88%) 3 |
| Hyponatraemia subjects affected / exposed occurrences (all) | 2 / 335 (0.60%) 2 | 1 / 178 (0.56%) 1 | 0 / 340 (0.00%) 0 |
| Alcohol intolerance subjects affected / exposed occurrences (all) | 0 / 335 (0.00%) 0 | 0 / 178 (0.00%) 0 | 0 / 340 (0.00%) 0 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Gout | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 2 / 340 (0.59%) |
| occurrences (all) | 1 | 0 | 2 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 3 / 178 (1.69%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 4 | 1 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypovitaminosis | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Selenium deficiency | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin A deficiency | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 1 / 178 (0.56%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vitamin E deficiency | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Malnutrition | | | |
| subjects affected / exposed | 2 / 335 (0.60%) | 1 / 178 (0.56%) | 2 / 340 (0.59%) |
| occurrences (all) | 2 | 1 | 2 |
| Vitamin K deficiency | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 1 / 178 (0.56%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 1 | 1 |
| Diabetes mellitus | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolic acidosis | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyponatraemic syndrome | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Underweight | | | |
| subjects affected / exposed | 1 / 335 (0.30%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 1 / 340 (0.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight gain poor | | | |
| subjects affected / exposed | 0 / 335 (0.00%) | 0 / 178 (0.00%) | 0 / 340 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Arm 4: Part A - Placebo - LUM 400 mg q12h/ IVA 250 mg q12h | Arm 5: Part A Observational Cohort | Arm 6: Part B LUM 400 mg q12h/ IVA 250 mg q12h |
|--|---|---------------------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 173 / 176 (98.30%) | 0 / 19 (0.00%) | 52 / 55 (94.55%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign breast neoplasm | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Melanocytic naevus | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lipoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Metastases to bone | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neurofibroma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seborrhoeic keratosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 3 | 0 | 1 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral coldness | | | |

| | | | |
|--|-------------------|----------------|-----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Phlebitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vasodilatation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombophlebitis superficial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Surgical and medical procedures | | | |
| Ethmoid sinus surgery | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wisdom teeth removal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 31 / 176 (17.61%) | 0 / 19 (0.00%) | 6 / 55 (10.91%) |
| occurrences (all) | 44 | 0 | 6 |
| Fatigue | | | |
| subjects affected / exposed | 22 / 176 (12.50%) | 0 / 19 (0.00%) | 7 / 55 (12.73%) |
| occurrences (all) | 26 | 0 | 9 |
| Pain | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 3 | 0 | 1 |
| Malaise | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 1 | 0 | 1 |
| Chest discomfort | | | |

| | | | |
|------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Feeling cold | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Application site vesicles | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Catheter site haematoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vessel puncture site bruise | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Application site irritation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Catheter site rash | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Drug intolerance | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Drug withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Facial pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hernia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hunger | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infusion site bruising | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion site pruritus | | | |

| | | | |
|-----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mass | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Medical device pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Medical device site ulcer | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vessel puncture site pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vessel puncture site phlebitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion site inflammation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Local swelling | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Medical device site extravasation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Seasonal allergy | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 5 | 0 | 3 |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Allergy to arthropod bite | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergy to animal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergy to arthropod sting | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| House dust allergy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunisation reaction | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mycotic allergy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reaction to food additive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Serum sickness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Smoke sensitivity | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|----------------|----------------|
| Social circumstances | | | |
| Menopause | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Metrorrhagia | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Abnormal withdrawal bleeding | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cervical polyp | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menstruation irregular | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Menorrhagia | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Vaginal discharge | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polycystic ovaries | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast tenderness | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endometriosis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal pruritus | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acquired hydrocele | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adnexa uteri mass | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amenorrhoea | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bartholin's cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erectile dysfunction | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ovarian cyst ruptured | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ovarian hyperfunction | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polymenorrhoea | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus genital | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectocele | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Testicular cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Testicular pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Uterine prolapse | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal inflammation | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vulvovaginal discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |

| | | | |
|--------------------------------|-------------------|----------------|------------------|
| subjects affected / exposed | 82 / 176 (46.59%) | 0 / 19 (0.00%) | 18 / 55 (32.73%) |
| occurrences (all) | 166 | 0 | 24 |
| Sputum increased | | | |
| subjects affected / exposed | 37 / 176 (21.02%) | 0 / 19 (0.00%) | 11 / 55 (20.00%) |
| occurrences (all) | 60 | 0 | 11 |
| Haemoptysis | | | |
| subjects affected / exposed | 29 / 176 (16.48%) | 0 / 19 (0.00%) | 8 / 55 (14.55%) |
| occurrences (all) | 49 | 0 | 20 |
| Dyspnoea | | | |
| subjects affected / exposed | 36 / 176 (20.45%) | 0 / 19 (0.00%) | 9 / 55 (16.36%) |
| occurrences (all) | 48 | 0 | 11 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 22 / 176 (12.50%) | 0 / 19 (0.00%) | 8 / 55 (14.55%) |
| occurrences (all) | 26 | 0 | 10 |
| Respiration abnormal | | | |
| subjects affected / exposed | 25 / 176 (14.20%) | 0 / 19 (0.00%) | 7 / 55 (12.73%) |
| occurrences (all) | 34 | 0 | 8 |
| Nasal congestion | | | |
| subjects affected / exposed | 23 / 176 (13.07%) | 0 / 19 (0.00%) | 8 / 55 (14.55%) |
| occurrences (all) | 30 | 0 | 13 |
| Productive cough | | | |
| subjects affected / exposed | 13 / 176 (7.39%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 14 | 0 | 3 |
| Sinus congestion | | | |
| subjects affected / exposed | 12 / 176 (6.82%) | 0 / 19 (0.00%) | 7 / 55 (12.73%) |
| occurrences (all) | 15 | 0 | 10 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 11 | 0 | 2 |
| Wheezing | | | |
| subjects affected / exposed | 12 / 176 (6.82%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 13 | 0 | 3 |
| Paranasal sinus hypersecretion | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 7 | 0 | 3 |
| Respiratory tract congestion | | | |

| | | | |
|------------------------------------|------------------|----------------|----------------|
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 5 / 55 (9.09%) |
| occurrences (all) | 4 | 0 | 7 |
| Asthma | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 5 | 0 | 3 |
| Lower respiratory tract congestion | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Rales | | | |
| subjects affected / exposed | 11 / 176 (6.25%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 13 | 0 | 1 |
| Sputum discoloured | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Bronchospasm | | | |
| subjects affected / exposed | 8 / 176 (4.55%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 9 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 4 | 0 | 1 |
| Nasal polyps | | | |
| subjects affected / exposed | 9 / 176 (5.11%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 9 | 0 | 1 |
| Pleuritic pain | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 6 | 0 | 1 |
| Dyspnoea exertional | | | |

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|--|-----------------|----------------|----------------|
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 4 | 0 | 1 |
| Increased viscosity of bronchial secretion | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Upper respiratory tract congestion | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Increased bronchial secretion | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Painful respiration | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 1 | 0 | 2 |
| Throat irritation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal discharge discolouration | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bronchiectasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paranasal sinus discomfort | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 1 | 0 | 1 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Lung infiltration | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|----------------------------------|-----------------|----------------|----------------|
| Nocturnal dyspnoea | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Obstructive airways disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal discomfort | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhinalgia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchial obstruction | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Bronchial secretion retention | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased upper airway secretion | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sneezing | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal oedema | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal mucosal disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleurisy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary pain | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|--------------------------------------|-----------------|----------------|----------------|
| Sinus disorder | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sputum retention | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal inflammation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Allergic sinusitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal septum deviation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|----------------|----------------|
| Rhonchi | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinus polyp | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acquired diaphragmatic eventration | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic respiratory disease | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic respiratory symptom | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchial irritation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchostenosis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperventilation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypopnoea | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Increased viscosity of upper respiratory secretion | | | |

| | | | |
|---------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung consolidation | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lung hyperinflation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal turbinate hypertrophy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Orthopnoea | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paranasal cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngeal oedema | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural fibrosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary bulla | | | |

| | | | |
|--------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reflux laryngitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract haemorrhage | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract irritation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Throat tightness | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillolith | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tracheal disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tracheal inflammation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |

| | | | |
|--|-----------------|----------------|----------------|
| Anxiety | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 4 | 0 | 1 |
| Insomnia | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Depressed mood | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Attention deficit/hyperactivity disorder | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stress | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adjustment disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adjustment disorder with anxiety | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Agitation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased interest | | | |

| | | | |
|---------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disturbance in social behaviour | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Encopresis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Food aversion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hallucination, visual | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intentional self-injury | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Listless | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nervousness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Obsessive-compulsive disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Somnambulism | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Depression | | | |

| | | | |
|---|------------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 10 / 176 (5.68%) 10 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Product issues | | | |
| Device dislocation subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Device occlusion subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Device leakage subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 2 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Hepatobiliary disorders | | | |
| Cholecystitis subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Jaundice subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Cholelithiasis subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Biliary colic subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Hepatomegaly subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Cholecystitis chronic subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Hepatic pain subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Hepatic steatosis | | | |

| | | | |
|--|------------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Investigations | | | |
| Pulmonary function test decreased subjects affected / exposed occurrences (all) | 15 / 176 (8.52%) 17 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Blood creatine phosphokinase increased subjects affected / exposed occurrences (all) | 15 / 176 (8.52%) 18 | 0 / 19 (0.00%) 0 | 5 / 55 (9.09%) 5 |
| Forced expiratory volume decreased subjects affected / exposed occurrences (all) | 15 / 176 (8.52%) 22 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Bacterial test positive subjects affected / exposed occurrences (all) | 11 / 176 (6.25%) 15 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 15 / 176 (8.52%) 18 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 13 / 176 (7.39%) 14 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Blood glucose decreased subjects affected / exposed occurrences (all) | 2 / 176 (1.14%) 2 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) | 2 / 176 (1.14%) 2 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Weight decreased subjects affected / exposed occurrences (all) | 3 / 176 (1.70%) 3 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Blood creatinine increased subjects affected / exposed occurrences (all) | 7 / 176 (3.98%) 8 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Blood glucose increased | | | |

| | | | |
|--------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Fungal test positive | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Vitamin D decreased | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Liver function test increased | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| White blood cell count increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Atypical mycobacterium test positive | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Influenza A virus test positive | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Neutrophil count increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood magnesium decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Clostridium test positive | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oxygen saturation decreased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cells urine positive | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood bicarbonate decreased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood immunoglobulin E increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Body temperature increased | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Crystal urine present | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Protein urine present | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Staphylococcus test positive | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood calcium increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood potassium increased | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood pressure systolic increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood thyroid stimulating hormone increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Breath sounds abnormal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eosinophil count increased | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Forced vital capacity decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glucose urine present | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glycosylated haemoglobin increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Monocyte count increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pseudomonas test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|----------------|----------------|
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Candida test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Glucose tolerance test abnormal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human rhinovirus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood albumin decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood immunoglobulin G increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood iron decreased | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood potassium decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Helicobacter test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza virus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reticulocyte percentage increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Sputum abnormal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory syncytial virus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aspergillus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|---------------------|---------------------|
| Blood androstenedione increased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood cholesterol increased subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood cortisol decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood creatine increased subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood glucose fluctuation subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood magnesium increased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood phosphorus decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood phosphorus increased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood sodium decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood sodium increased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood testosterone decreased subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood testosterone increased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |

| | | | |
|--|-----------------|----------------|----------------|
| Blood urine present | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Burkholderia test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Citrobacter test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Computerised tomogram thorax abnormal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coronavirus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydroepiandrosterone increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram PR shortened | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Electrocardiogram ST segment elevation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram abnormal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epstein-Barr virus antibody positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Escherichia test positive | | | |

| | | | |
|-------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Grip strength decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoglobin increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human metapneumovirus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human papilloma virus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mean cell volume increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myoglobin blood increased | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Precancerous cells present | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Red blood cells urine positive | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reticulocyte count increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rubulavirus test positive | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ultrasound liver abnormal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|---------------------|---------------------|
| Urine analysis abnormal subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Urine bilirubin increased subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Urine ketone body present subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Viral test positive subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Vitamin A decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Vitamin B12 decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Vitamin E decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| White blood cell count decreased subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion subjects affected / exposed occurrences (all) | 3 / 176 (1.70%) 3 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Procedural pain subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Ligament sprain subjects affected / exposed occurrences (all) | 6 / 176 (3.41%) 8 | 0 / 19 (0.00%) 0 | 2 / 55 (3.64%) 2 |
| Muscle strain | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 1 | 0 | 1 |
| Arthropod bite | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 1 | 0 | 2 |
| Laceration | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rib fracture | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sunburn | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 1 | 0 | 2 |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Periorbital haemorrhage | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Post procedural swelling | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Foot fracture | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chest injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post-traumatic pain | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Facial bones fracture | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Back injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sports injury | | | |

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|--------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial injury of eye | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Animal bite | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthropod sting | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Incisional hernia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post procedural discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural nausea | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stoma site discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site irritation | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Traumatic haematoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Accidental exposure to product | | | |

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| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Animal scratch | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ankle fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Avulsion fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusion postoperative | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epicondylitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Excoriation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face injury | | | |

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|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Forearm fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heat stroke | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Incision site haematoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb crushing injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nerve injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral nerve injury | | | |

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|------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural anxiety | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural headache | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural vomiting | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus barotrauma | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Soft tissue injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Splinter | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site erythema | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site haemorrhage | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site ulcer | | | |

| | | | |
|--|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stress fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Thyroglossal cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystic fibrosis related diabetes | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Cystic fibrosis hepatic disease | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystic fibrosis lung | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermoid cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Naevus flammeus | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |

| | | | |
|-------------------------------------|-------------------|----------------|-----------------|
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ventricular extrasystoles | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus arrhythmia | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Extrasystoles | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Left ventricular hypertrophy | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 22 / 176 (12.50%) | 0 / 19 (0.00%) | 7 / 55 (12.73%) |
| occurrences (all) | 31 | 0 | 7 |
| Sinus headache | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 3 | 0 | 3 |
| Dizziness | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 6 | 0 | 1 |

| | | | |
|---------------------------------|-----------------|----------------|----------------|
| Migraine | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 3 | 0 | 1 |
| Lethargy | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Paraesthesia | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anosmia | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Circadian rhythm sleep disorder | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Migraine with aura | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neuralgia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tension headache | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ageusia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aphonia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coordination abnormal | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyposmia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intercostal neuralgia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|----------------------|---------------------|---------------------|
| Nerve compression subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Neuropathy peripheral subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Nystagmus subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Olfactory nerve disorder subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Disturbance in attention subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 2 / 176 (1.14%) 2 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Eosinophilia subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Anaemia subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Splenomegaly subjects affected / exposed occurrences (all) | 2 / 176 (1.14%) 2 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Bone marrow oedema subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Haemoconcentration | | | |

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|------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Macrocytosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Cerumen impaction | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Deafness neurosensory | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|----------------------|---------------------|---------------------|
| Deafness unilateral subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Ear congestion subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Ear pruritus subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Middle ear effusion subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Motion sickness subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Ototoxicity subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Tympanic membrane perforation subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Vestibular disorder subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Ear discomfort subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Eye disorders | | | |
| Blepharospasm subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Vision blurred | | | |

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|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Eye pruritus | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye swelling | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular hyperaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diabetic retinopathy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual acuity reduced | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye haemorrhage | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glaucoma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myopia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ulcerative keratitis | | | |

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|--|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 28 / 176 (15.91%) | 0 / 19 (0.00%) | 5 / 55 (9.09%) |
| occurrences (all) | 41 | 0 | 7 |
| Nausea | | | |
| subjects affected / exposed | 27 / 176 (15.34%) | 0 / 19 (0.00%) | 5 / 55 (9.09%) |
| occurrences (all) | 30 | 0 | 6 |
| Abdominal pain | | | |
| subjects affected / exposed | 15 / 176 (8.52%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 18 | 0 | 3 |
| Constipation | | | |
| subjects affected / exposed | 10 / 176 (5.68%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 12 | 0 | 3 |
| Vomiting | | | |
| subjects affected / exposed | 13 / 176 (7.39%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 16 | 0 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 11 / 176 (6.25%) | 0 / 19 (0.00%) | 6 / 55 (10.91%) |
| occurrences (all) | 11 | 0 | 6 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 5 / 55 (9.09%) |
| occurrences (all) | 4 | 0 | 5 |
| Flatulence | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 6 | 0 | 1 |
| Abdominal distension | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 4 | 0 | 1 |
| Toothache | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |

| | | | |
|--|-----------------|----------------|----------------|
| Abdominal discomfort | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Distal intestinal obstruction syndrome | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dental discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip swelling | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pancreatitis acute | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Post-tussive vomiting | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Steatorrhoea | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Frequent bowel movements | | | |

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|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Enteritis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth impacted | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bowel movement irregularity | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Breath odour | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hiatus hernia | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Varices oesophageal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal fistula | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic gastritis | | | |

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|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulum intestinal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epigastric discomfort | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faecal volume decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faecal volume increased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faeces soft | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastric mucosal hypertrophy | | | |

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|------------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal motility disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival erythema | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival recession | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis ulcerative | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glossitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glossodynia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intussusception | | | |

| | | | |
|---------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malabsorption | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malpositioned teeth | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mucous stools | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal irritation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal mucosal hyperplasia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral mucosal blistering | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |

| | | | |
|--|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral papule | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pancreatic insufficiency | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumoperitoneum | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reflux gastritis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Retching | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth delamination | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Umbilical hernia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Acne | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Pruritus | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Urticaria | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 4 | 0 | 2 |
| Dermatitis contact | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 7 | 0 | 1 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Red man syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pruritus allergic | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Rash papular | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Swelling face | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Skin exfoliation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hand dermatitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin mass | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin warm | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Solar dermatitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne cystic | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blister | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fixed drug eruption | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypersensitivity vasculitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Keratosis pilaris | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Madarosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Purpura senile | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash morbilliform | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rosacea | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scar pain | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin irritation | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin wrinkling | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticarial vasculitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Stress urinary incontinence | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nephrolithiasis | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Chromaturia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic kidney disease | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nocturia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Calculus urinary | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glycosuria | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypernatruria | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocitraturia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------|-----------------|----------------|----------------|
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyelocaliectasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal hypertrophy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal tubular disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary retention | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine abnormality | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Goitre | | | |

| | | | |
|---|------------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Growth hormone deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Androgen deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cushing's syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 13 / 176 (7.39%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 15 | 0 | 7 |
| Back pain | | | |
| subjects affected / exposed | 10 / 176 (5.68%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 12 | 0 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 6 | 0 | 1 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 3 | 0 | 2 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 2 | 0 | 2 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |

| | | | |
|----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Osteopenia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 0 | 0 | 3 |
| Arthropathy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteoporosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Bursitis | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc degeneration | | | |

| | | | |
|----------------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint stiffness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pathological fracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenosynovitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Medial tibial stress syndrome | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Osteochondrosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polyarthritis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal pain | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Exostosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint range of motion decreased | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Juvenile idiopathic arthritis | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Muscle contracture | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle tightness | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia intercostal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Plantar fasciitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendon pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Torticollis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chondropathy | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coccydynia | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc annular tear | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mastication disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle fatigue | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle oedema | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Scoliosis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tendon disorder | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Infective pulmonary exacerbation of cystic fibrosis | | | |

| | | | |
|---|-------------------|----------------|------------------|
| subjects affected / exposed | 91 / 176 (51.70%) | 0 / 19 (0.00%) | 18 / 55 (32.73%) |
| occurrences (all) | 193 | 0 | 32 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 27 / 176 (15.34%) | 0 / 19 (0.00%) | 6 / 55 (10.91%) |
| occurrences (all) | 49 | 0 | 9 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 29 / 176 (16.48%) | 0 / 19 (0.00%) | 7 / 55 (12.73%) |
| occurrences (all) | 38 | 0 | 12 |
| Sinusitis | | | |
| subjects affected / exposed | 13 / 176 (7.39%) | 0 / 19 (0.00%) | 7 / 55 (12.73%) |
| occurrences (all) | 21 | 0 | 7 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 10 / 176 (5.68%) | 0 / 19 (0.00%) | 3 / 55 (5.45%) |
| occurrences (all) | 25 | 0 | 3 |
| Influenza | | | |
| subjects affected / exposed | 15 / 176 (8.52%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 16 | 0 | 2 |
| Rhinitis | | | |
| subjects affected / exposed | 12 / 176 (6.82%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 20 | 0 | 1 |
| Upper respiratory tract infection bacterial | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 8 | 0 | 2 |
| Bronchitis | | | |
| subjects affected / exposed | 8 / 176 (4.55%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 19 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 9 / 176 (5.11%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 13 | 0 | 2 |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 7 / 176 (3.98%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 7 | 0 | 2 |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 6 | 0 | 1 |

| | | | |
|---|-----------------|----------------|----------------|
| Pharyngitis | | | |
| subjects affected / exposed | 8 / 176 (4.55%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 13 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 6 | 0 | 3 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 10 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 5 / 176 (2.84%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 6 | 0 | 2 |
| Bronchopulmonary aspergillosis allergic | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 8 | 0 | 4 |
| Otitis media | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 1 | 0 | 2 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Lung infection pseudomonal | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 4 | 0 | 3 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 2 |
| Respiratory tract infection bacterial | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 4 / 176 (2.27%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 1 | 0 | 1 |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bacterial disease carrier | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Ear infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Kidney infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Onychomycosis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchopulmonary aspergillosis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Fungal skin infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Genital candidiasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes dermatitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinusitis bacterial | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stoma site infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tinea infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|----------------------|---------------------|---------------------|
| Hand-foot-and-mouth disease subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Herpes zoster subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 1 / 55 (1.82%) 1 |
| Infectious mononucleosis subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Mycobacterial disease carrier subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Superinfection bacterial subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Gastrointestinal viral infection subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Infective exacerbation of bronchiectasis subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Mycobacterium abscessus infection subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Oropharyngitis fungal subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Otitis externa fungal subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Parotitis subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Vaginal infection | | | |

| | | | |
|--|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Tracheitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Varicella | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral pharyngitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wound infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acne pustular | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adenoiditis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angular cheilitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthritis infective | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atypical mycobacterial lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|----------------------|---------------------|---------------------|
| Atypical mycobacterial pneumonia subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Bacterial vaginosis subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Bronchitis fungal subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Clostridium difficile infection subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Conjunctivitis viral subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Epididymitis subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Erythema infectiosum subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Febrile infection subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Fungal infection subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Furuncle subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Gastroenteritis norovirus subjects affected / exposed occurrences (all) | 1 / 176 (0.57%) 1 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |
| Genital herpes subjects affected / exposed occurrences (all) | 0 / 176 (0.00%) 0 | 0 / 19 (0.00%) 0 | 0 / 55 (0.00%) 0 |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| Genital herpes simplex | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Genital infection fungal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin abscess | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemophilus infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Helicobacter infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatitis C | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Implant site infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral bacterial infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|-----------------|----------------|----------------|
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Overgrowth bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Overgrowth fungal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Papilloma viral infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pseudomonas bronchitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Salpingo-oophoritis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection fungal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---------------------------------------|-----------------|----------------|----------------|
| Sepsis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin bacterial infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Small intestinal bacterial overgrowth | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sputum purulent | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tracheobronchitis | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Trichomoniasis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory fungal infection | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection enterococcal | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginitis bacterial | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginitis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|-----------------|----------------|----------------|
| Metabolism and nutrition disorders | | | |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 6 / 176 (3.41%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 6 | 0 | 1 |
| Decreased appetite | | | |
| subjects affected / exposed | 9 / 176 (5.11%) | 0 / 19 (0.00%) | 2 / 55 (3.64%) |
| occurrences (all) | 10 | 0 | 2 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 3 / 176 (1.70%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 3 | 0 | 1 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 2 |
| Iron deficiency | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Glucose tolerance impaired | | | |
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 1 | 0 | 1 |
| Alcohol intolerance | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Gout | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 2 | 0 | 1 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 2 / 176 (1.14%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypovitaminosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Selenium deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Vitamin A deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Vitamin E deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 1 / 55 (1.82%) |
| occurrences (all) | 0 | 0 | 1 |
| Malnutrition | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitamin K deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diabetes mellitus | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemic syndrome | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Underweight | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 0 / 176 (0.00%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight gain poor | | | |
| subjects affected / exposed | 1 / 176 (0.57%) | 0 / 19 (0.00%) | 0 / 55 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|--|--|
| Non-serious adverse events | Arm 7: Part B - Placebo - LUM 400 mg q12h/ IVA 250 mg q12h | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 57 / 60 (95.00%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign breast neoplasm | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Melanocytic naevus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lipoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malignant melanoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metastases to bone | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neurofibroma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seborrhoeic keratosis | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Hot flush | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Flushing | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral coldness | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Phlebitis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Vasodilatation | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |

| | | | |
|--|-----------------------|--|--|
| Thrombophlebitis superficial subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Thrombosis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Surgical and medical procedures | | | |
| Ethmoid sinus surgery subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Wisdom teeth removal subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| General disorders and administration site conditions | | | |
| Pyrexia subjects affected / exposed occurrences (all) | 8 / 60 (13.33%) 10 | | |
| Fatigue subjects affected / exposed occurrences (all) | 6 / 60 (10.00%) 6 | | |
| Pain subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Malaise subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Chest discomfort subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Chest pain subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Asthenia subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Chills | | | |

| | | | |
|------------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Feeling cold | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Application site vesicles | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Catheter site haematoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Catheter site pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exercise tolerance decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral swelling | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Sensation of foreign body | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vessel puncture site bruise | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Application site irritation | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Catheter site rash | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Drug intolerance | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Drug withdrawal syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Face oedema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Facial pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hernia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hunger | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infusion site bruising | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infusion site pruritus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mass | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Medical device pain | | | |

| | | | |
|-----------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Medical device site ulcer | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaccination site pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vessel puncture site pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vessel puncture site phlebitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infusion site inflammation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Local swelling | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Medical device site extravasation | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 4 | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---------------------|--|--|
| Allergy to arthropod bite subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Allergy to animal subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Allergy to arthropod sting subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| House dust allergy subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Immunisation reaction subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Mycotic allergy subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Reaction to food additive subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Serum sickness subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Smoke sensitivity subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Social circumstances Menopause subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Metrorrhagia | | | |

| | | | |
|------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abnormal withdrawal bleeding | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Cervical polyp | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Menstruation irregular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Menorrhagia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal discharge | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polycystic ovaries | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Breast tenderness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Endometriosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Uterine haemorrhage | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulvovaginal pruritus | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acquired hydrocele | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Adnexa uteri mass | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Amenorrhoea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bartholin's cyst | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erectile dysfunction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ovarian cyst ruptured | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ovarian hyperfunction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polymenorrhoea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pruritus genital | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rectocele | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Testicular cyst | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Testicular pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Uterine prolapse | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal inflammation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulvovaginal discomfort | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vulvovaginal pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 18 / 60 (30.00%) | | |
| occurrences (all) | 35 | | |
| Sputum increased | | | |
| subjects affected / exposed | 18 / 60 (30.00%) | | |
| occurrences (all) | 23 | | |
| Haemoptysis | | | |
| subjects affected / exposed | 10 / 60 (16.67%) | | |
| occurrences (all) | 17 | | |
| Dyspnoea | | | |

| | | | |
|------------------------------------|------------------|--|--|
| subjects affected / exposed | 13 / 60 (21.67%) | | |
| occurrences (all) | 14 | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 7 / 60 (11.67%) | | |
| occurrences (all) | 9 | | |
| Respiration abnormal | | | |
| subjects affected / exposed | 21 / 60 (35.00%) | | |
| occurrences (all) | 24 | | |
| Nasal congestion | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 4 | | |
| Productive cough | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Sinus congestion | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 4 | | |
| Wheezing | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Paranasal sinus hypersecretion | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Lower respiratory tract congestion | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 5 | | |
| Rales | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Sputum discoloured | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Dysphonia | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal polyps | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pleuritic pain | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 7 | | |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 3 | | |
| Increased viscosity of bronchial secretion | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Upper respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|---------------------|--|--|
| Increased bronchial secretion subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Painful respiration subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Throat irritation subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Nasal discharge discolouration subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Bronchiectasis subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Hypoxia subjects affected / exposed occurrences (all) | 2 / 60 (3.33%) 2 | | |
| Paranasal sinus discomfort subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Bronchial hyperreactivity subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Lung infiltration subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Nocturnal dyspnoea subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Obstructive airways disorder subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Oropharyngeal discomfort subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |

| | | | |
|--------------------------------------|----------------|--|--|
| Rhinalgia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Bronchial obstruction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchial secretion retention | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Increased upper airway secretion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sneezing | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal oedema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal mucosal disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pleurisy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sputum retention | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal inflammation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumothorax spontaneous | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Allergic sinusitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lung disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal septum deviation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhonchi | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus polyp | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sleep apnoea syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | | |
|---|----------------|--|--|--|
| Acquired diaphragmatic eventration | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Allergic cough | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Allergic respiratory disease | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Allergic respiratory symptom | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Bronchial irritation | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Bronchostenosis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hyperventilation | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hypopnoea | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Increased viscosity of upper respiratory secretion | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Lung consolidation | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Lung hyperinflation | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nasal discomfort | | | | |

| | | | |
|---------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal turbinate hypertrophy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Orthopnoea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Paranasal cyst | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngeal oedema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pleural fibrosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary arterial hypertension | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary bulla | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary hypertension | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reflux laryngitis | | | |

| | | | |
|--------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract haemorrhage | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract irritation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Throat tightness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tonsillolith | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tracheal disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tracheal inflammation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Depressed mood | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | | |
|--|----------------|--|--|--|
| Panic attack | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Attention deficit/hyperactivity disorder | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Stress | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Adjustment disorder | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Adjustment disorder with anxiety | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Adjustment disorder with depressed mood | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Agitation | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Confusional state | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Decreased interest | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Disturbance in social behaviour | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Encopresis | | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Food aversion | | | | |

| | | | |
|-------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hallucination, visual | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intentional self-injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Listless | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nervousness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Obsessive-compulsive disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Somnambulism | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Depression | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Product issues | | | |
| Device dislocation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Device occlusion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|------------------------|--|--|
| Device leakage subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Hepatobiliary disorders | | | |
| Cholecystitis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Jaundice subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Cholelithiasis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Biliary colic subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Hepatomegaly subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Cholecystitis chronic subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Hepatic pain subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Hepatic steatosis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Investigations | | | |
| Pulmonary function test decreased subjects affected / exposed occurrences (all) | 3 / 60 (5.00%) 3 | | |
| Blood creatine phosphokinase increased subjects affected / exposed occurrences (all) | 10 / 60 (16.67%) 10 | | |
| Forced expiratory volume decreased | | | |

| | | | |
|--------------------------------------|-----------------|--|--|
| subjects affected / exposed | 7 / 60 (11.67%) | | |
| occurrences (all) | 7 | | |
| Bacterial test positive | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 4 | | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 7 / 60 (11.67%) | | |
| occurrences (all) | 7 | | |
| Blood glucose decreased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Blood glucose increased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Fungal test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin D decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Liver function test increased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |

| | | | |
|---|---------------------|--|--|
| White blood cell count increased subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Atypical mycobacterium test positive subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Influenza A virus test positive subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Neutrophil count increased subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all) | 2 / 60 (3.33%) 2 | | |
| Blood magnesium decreased subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Clostridium test positive subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Oxygen saturation decreased subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Transaminases increased subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Blood bicarbonate decreased | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood immunoglobulin E increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Body temperature increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Crystal urine present | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemoglobin decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Protein urine present | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Staphylococcus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood calcium increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood potassium increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood pressure systolic increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood thyroid stimulating hormone increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood urea increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---------------------------------------|----------------|--|--|
| Breath sounds abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eosinophil count increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Forced vital capacity decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glucose urine present | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glycosylated haemoglobin increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Monocyte count increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pseudomonas test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood pressure increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Candida test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Electrocardiogram QT prolonged | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glucose tolerance test abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Heart rate increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Human rhinovirus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza B virus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood albumin decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood immunoglobulin G increased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Blood iron decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood potassium decreased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Helicobacter test positive | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Influenza virus test positive | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|----------------|--|--|
| Lymphocyte count increased | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |
| Reticulocyte percentage increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sputum abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Platelet count increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Prothrombin time prolonged | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory syncytial virus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Weight increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aspergillus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood androstenedione increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood cholesterol increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood cortisol decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood creatine increased | | | |

| | | | |
|------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood glucose fluctuation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood magnesium increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood phosphorus decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood phosphorus increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood sodium decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood sodium increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood testosterone decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood testosterone increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Burkholderia test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Citrobacter test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Computerised tomogram thorax | | | |

| | | | |
|--|----------------|--|--|
| abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Coronavirus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dehydroepiandrosterone increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Electrocardiogram PR shortened | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Electrocardiogram ST segment elevation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Electrocardiogram abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epstein-Barr virus antibody positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Escherichia test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Grip strength decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemoglobin increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Human metapneumovirus test positive | | | |

| | | | |
|-------------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Human papilloma virus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mean cell volume increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myoglobin blood increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Precancerous cells present | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Red blood cells urine positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reticulocyte count increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rubulavirus test positive | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ultrasound liver abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urine analysis abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urine bilirubin increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urine ketone body present | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral test positive | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin A decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin B12 decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin E decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural pain | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 3 | | |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle strain | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laceration | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fall | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rib fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Concussion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sunburn | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Periorbital haemorrhage | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post procedural swelling | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Skin abrasion | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Foot fracture | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chest injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post-traumatic pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Facial bones fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Back injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ligament injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sports injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Superficial injury of eye | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arthropod sting | | | |

| | | | |
|--------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Incisional hernia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post procedural discomfort | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural nausea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site discomfort | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site irritation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Traumatic haematoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wrist fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Accidental exposure to product | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Animal scratch | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ankle fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Avulsion fracture | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Confusion postoperative | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Corneal abrasion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epicondylitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Excoriation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exposure to toxic agent | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Face injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Forearm fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Head injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Heat stroke | | | |

| | | | |
|------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Incision site haematoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Limb crushing injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lip injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle rupture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neck injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nerve injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral nerve injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural anxiety | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural headache | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural vomiting | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus barotrauma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Soft tissue injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Splinter | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site erythema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site haemorrhage | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stress fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wound | | | |

| | | | |
|--|---------------------|--|--|
| subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Congenital, familial and genetic disorders | | | |
| Thyroglossal cyst subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Cystic fibrosis related diabetes subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Cystic fibrosis hepatic disease subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Cystic fibrosis lung subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Dermoid cyst subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Naevus flammeus subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Cardiac disorders | | | |
| Cyanosis subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Palpitations subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Tachycardia subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Ventricular extrasystoles | | | |

| | | | |
|-------------------------------------|-----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus arrhythmia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Extrasystoles | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atrioventricular block first degree | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Left ventricular hypertrophy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ventricular tachycardia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 7 / 60 (11.67%) | | |
| occurrences (all) | 7 | | |
| Sinus headache | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Dizziness | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Migraine | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lethargy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---------------------------------|----------------|--|--|
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anosmia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Somnolence | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Circadian rhythm sleep disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Migraine with aura | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neuralgia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Presyncope | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sciatica | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seizure | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Tension headache | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tremor | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ageusia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aphonia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Coordination abnormal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyposmia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intercostal neuralgia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nerve compression | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nystagmus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|---------------------|--|--|
| Olfactory nerve disorder subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Disturbance in attention subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Eosinophilia subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Anaemia subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Splenomegaly subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Bone marrow oedema subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Haemoconcentration subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Increased tendency to bruise subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Leukocytosis | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Macrocytosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vertigo | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Cerumen impaction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Deafness unilateral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear congestion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear pruritus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---------------------|--|--|
| Middle ear effusion subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Motion sickness subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Ototoxicity subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Tympanic membrane perforation subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Vestibular disorder subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Ear discomfort subjects affected / exposed occurrences (all) | 2 / 60 (3.33%) 2 | | |
| Eye disorders | | | |
| Blepharospasm subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Vision blurred subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Dry eye subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Eye pruritus subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Lacrimation increased | | | |

| | | | |
|-----------------------------|-----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye swelling | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ocular hyperaemia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diabetic retinopathy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Visual acuity reduced | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye haemorrhage | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glaucoma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myopia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ulcerative keratitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 9 / 60 (15.00%) | | |
| occurrences (all) | 11 | | |
| Nausea | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 5 | | |

| | | | |
|--|----------------|--|--|
| Abdominal pain | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Constipation | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Vomiting | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 4 | | |
| Flatulence | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Toothache | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |
| Distal intestinal obstruction syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dental discomfort | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Lip swelling | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Pancreatitis acute | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post-tussive vomiting | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Steatorrhoea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Faecaloma | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry mouth | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Enteritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Inguinal hernia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth impacted | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aphthous ulcer | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bowel movement irregularity | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Breath odour | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ileus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mouth ulceration | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Varices oesophageal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal fistula | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Barrett's oesophagus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cheilitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chronic gastritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dental caries | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhoea haemorrhagic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diverticulum intestinal | | | |

| | | | |
|------------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Duodenal ulcer | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epigastric discomfort | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eructation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Faecal volume decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Faecal volume increased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Faeces soft | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastric mucosal hypertrophy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal motility disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingival bleeding | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingival erythema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingival recession | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingivitis ulcerative | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glossitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glossodynia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemorrhoids thrombosed | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Impaired gastric emptying | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intussusception | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Irritable bowel syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malabsorption | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malpositioned teeth | | | |

| | | | |
|---------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Melaena | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mucous stools | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oesophageal irritation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oesophageal mucosal hyperplasia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral mucosal blistering | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral papule | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pancreatic insufficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumoperitoneum | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reflux gastritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Retching | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Salivary hypersecretion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth delamination | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Umbilical hernia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Acne | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pruritus | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 4 | | |
| Night sweats | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Urticaria | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Alopecia | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Drug eruption | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Red man syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pruritus allergic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash papular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry skin | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Dermatitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain of skin | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Swelling face | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash macular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin exfoliation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand dermatitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ingrowing nail | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Petechiae | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin mass | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin warm | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Solar dermatitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acne cystic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blister | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|----------------|--|--|
| Fixed drug eruption | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Henoch-Schonlein purpura | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypersensitivity vasculitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Keratosis pilaris | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Madarosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Purpura senile | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash morbilliform | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash pruritic | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rosacea | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Scar pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin irritation | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin wrinkling | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urticarial vasculitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Renal and urinary disorders | | | |
| Stress urinary incontinence | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chromaturia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Chronic kidney disease | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nocturia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Calculus urinary | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glycosuria | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematuria | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypernatruria | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypocitraturia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pyelocaliectasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Renal colic | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|------------------------------|----------------|--|--|
| Renal failure | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Renal hypertrophy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Renal pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Renal tubular disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tubulointerstitial nephritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary retention | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urine abnormality | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Goitre | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Growth hormone deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Androgen deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cushing's syndrome | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 8 / 60 (13.33%) | | |
| occurrences (all) | 11 | | |
| Back pain | | | |
| subjects affected / exposed | 5 / 60 (8.33%) | | |
| occurrences (all) | 5 | | |
| Myalgia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 4 | | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Osteopenia | | | |

| | | | |
|----------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arthropathy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Osteoporosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bursitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Groin pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Joint stiffness | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Pathological fracture | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Tenosynovitis | | | |

| | | | |
|----------------------------------|----------------|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |
| Medial tibial stress syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Osteochondrosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polyarthritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Spinal pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Temporomandibular joint syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exostosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint range of motion decreased | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Juvenile idiopathic arthritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle contracture | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle tightness | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal discomfort | | | |

| | | | |
|----------------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myalgia intercostal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Plantar fasciitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tendon pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Torticollis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bone pain | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chondropathy | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Coccydynia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intervertebral disc annular tear | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mastication disorder | | | |

| | | | |
|---|------------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle fatigue | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle oedema | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Scoliosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tendon disorder | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infections and infestations | | | |
| Infective pulmonary exacerbation of cystic fibrosis | | | |
| subjects affected / exposed | 20 / 60 (33.33%) | | |
| occurrences (all) | 28 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 6 / 60 (10.00%) | | |
| occurrences (all) | 10 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 6 / 60 (10.00%) | | |
| occurrences (all) | 9 | | |
| Sinusitis | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 4 / 60 (6.67%) | | |
| occurrences (all) | 5 | | |
| Influenza | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Upper respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |

| | | | |
|---|----------------|--|--|
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Bronchopulmonary aspergillosis allergic | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Otitis media | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lung infection pseudomonal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acute sinusitis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract infection bacterial | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral infection | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 2 | | |
| Pharyngitis streptococcal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Bacterial disease carrier | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lower respiratory tract infection bacterial | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cystitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |

| | | | |
|--------------------------------|----------------|--|--|
| Folliculitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lung infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Kidney infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Onychomycosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchopulmonary aspergillosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Clostridium difficile colitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fungal skin infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Genital candidiasis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Herpes dermatitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Hordeolum | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinusitis bacterial | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tinea infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchitis bacterial | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis bacterial | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---------------------|--|--|
| Mycobacterial disease carrier subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Superinfection bacterial subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Gastrointestinal viral infection subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Infective exacerbation of bronchiectasis subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Mycobacterium abscessus infection subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Oropharyngitis fungal subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 2 | | |
| Otitis externa fungal subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Parotitis subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Vaginal infection subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Tracheitis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Varicella subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Viral pharyngitis | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wound infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acarodermatitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acne pustular | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Adenoiditis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Angular cheilitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arthritis infective | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atypical mycobacterial lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atypical mycobacterial pneumonia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bacterial vaginosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchitis fungal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---------------------|--|--|
| Clostridium difficile infection subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Conjunctivitis viral subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Epididymitis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Erythema infectiosum subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Febrile infection subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Fungal infection subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Furuncle subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Gastroenteritis norovirus subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Genital herpes subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Genital herpes simplex subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Genital infection fungal subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Gingivitis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |

| | | | |
|-----------------------------|----------------|--|--|
| Groin abscess | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemophilus infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Helicobacter infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatitis C | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Impetigo | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Implant site infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Labyrinthitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Localised infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral bacterial infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Overgrowth bacterial | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Overgrowth fungal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|----------------|--|--|
| Papilloma viral infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonia staphylococcal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post procedural infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pseudomonas bronchitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Salpingo-oophoritis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory syncytial virus bronchitis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory tract infection fungal | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sepsis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin bacterial infection | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Small intestinal bacterial overgrowth | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|---------------------|--|--|
| Sputum purulent subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Tooth infection subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Tracheobronchitis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Trichomoniasis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Upper respiratory fungal infection subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Urinary tract infection enterococcal subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Vaginitis bacterial subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Vulvovaginitis subjects affected / exposed occurrences (all) | 0 / 60 (0.00%) 0 | | |
| Metabolism and nutrition disorders | | | |
| Vitamin D deficiency subjects affected / exposed occurrences (all) | 1 / 60 (1.67%) 1 | | |
| Decreased appetite subjects affected / exposed occurrences (all) | 3 / 60 (5.00%) 3 | | |
| Hypoglycaemia | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 2 / 60 (3.33%) | | |
| occurrences (all) | 2 | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 3 / 60 (5.00%) | | |
| occurrences (all) | 3 | | |
| Iron deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Glucose tolerance impaired | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Alcohol intolerance | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gout | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Hypovitaminosis | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | | |
| occurrences (all) | 1 | | |
| Selenium deficiency | | | |

| | | | |
|-----------------------------|----------------|--|--|
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin A deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin E deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malnutrition | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin K deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolic acidosis | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyponatraemic syndrome | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Underweight | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin B12 deficiency | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |
| Weight gain poor | | | |
| subjects affected / exposed | 0 / 60 (0.00%) | | |
| occurrences (all) | 0 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 05 February 2014 | - An additional mandatory testing to monitor the safety of liver function was added as a result of safety findings reported in Council for International Organizations of Medical Sciences (CIOMS) AE-2013-011098, dated 21 January 2014. |
| 22 September 2014 | - Included an exploratory, optional, non-interventional data collection for Part A Treatment Cohort subjects to collect respiratory culture results from the 12 months before the subject's first dose in Studies 103 (2012-003989-40) or 104 (2012-003990-24) through the end of the treatment period of Study 105 (2013-000604-41). - Reduced the frequency of liver function test (LFT) sample collection after Week 24. These changes were based on the review of interim safety data by both the sponsor and the data monitoring committee. - Updates were made to reflect that given the lack of overall efficacy, all subjects from Part B were to be notified of the results and that Vertex strongly recommended that all subjects from Part B be discontinued from Study 105 (2013-000604-41). If, in the opinion of the investigator, there were certain subjects for whom there was evidence of clinical benefit that outweighed potential risks, the investigator was to contact the Vertex medical monitor for approval to continue an individual subject in the study. - Updated that internal Vertex team could be un-blinded once all subjects reached Week 24 and data lock for interim analysis had occurred. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

| |
|--|
| Analysis using baseline values of the current study 105 (2013-000604-41) was not performed for Part B Treatment Cohort . |
|--|

Notes: