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)	EMEA-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 combintion 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 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 combintion 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 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	24.1	25.7	25.1
standard deviation	± 8.97	± 10.74	± 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 combintion 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 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.

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 combintion 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 (± 0.9)	3.1 (± 1.3)	3.7 (± 0.9)	1.5 (± 1.3)
Absolute Change at Week 72 (n= 265, 141, 269, 135)	3.2 (± 0.9)	3.3 (± 1.3)	5.7 (± 0.9)	3.3 (± 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 (± 18)	-4.1 (± 18.1)		
Absolute Change at Week 8 (n= 54, 57)	4.8 (± 18.6)	1 (± 18.2)		
Absolute Change at Week 16 (n= 51, 53)	6.2 (± 17.2)	-0.2 (± 17)		
Absolute Change at Week 24 (n= 39, 37)	6.8 (± 19.1)	-1.2 (± 17.9)		
Absolute Change at Week 48 (n= 19, 17)	2 (± 14)	4.9 (± 15.6)		
Absolute Change at Week 72 (n= 13, 15)	8.5 (± 21.8)	2.2 (± 18.8)		

Statistical analyses

No statistical analyses for this end point

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

No statistical analyses for this end point

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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=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: >=5% Change	21 (10.8 to 31.1)	12.7 (4.5 to 20.9)		
Week 8: >=5% Change	11.3 (3.4 to 19.2)	19 (9.4 to 28.7)		
Week 16: >=5% Change	19.4 (9.5 to 29.2)	15.9 (6.8 to 24.9)		
Week 24: >=5% Change	12.9 (4.6 to 21.2)	12.7 (4.5 to 20.9)		

Week 36: >=5% Change	6.5 (0.3 to 12.6)	6.3 (0.3 to 12.4)		
Week 48: >=5% Change	6.5 (0.3 to 12.6)	4.8 (0 to 10)		
Week 60: >=5% Change	6.5 (0.3 to 12.6)	6.3 (0.3 to 12.4)		
Week 72: >=5% Change	3.2 (0 to 7.6)	0 (0 to 0)		
Week 84: >=5% Change	1.6 (0 to 4.7)	1.6 (0 to 4.7)		
Week 96: >=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 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 combintion 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 n 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.

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 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.

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	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Malignant melanoma			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Metastases to bone			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Neurofibroma			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Seborrhoeic keratosis			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Skin papilloma			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 335 (0.90%)	2 / 178 (1.12%)	4 / 340 (1.18%)
occurrences (all)	3	4	5
Deep vein thrombosis			
subjects affected / exposed	3 / 335 (0.90%)	1 / 178 (0.56%)	2 / 340 (0.59%)
occurrences (all)	4	1	2
Hot flush			
subjects affected / exposed	1 / 335 (0.30%)	2 / 178 (1.12%)	1 / 340 (0.29%)
occurrences (all)	1	2	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	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Serum sickness			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Smoke sensitivity			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Menopause			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	6 / 335 (1.79%)	3 / 178 (1.69%)	8 / 340 (2.35%)
occurrences (all)	7	3	15
Metrorrhagia			
subjects affected / exposed	6 / 335 (1.79%)	2 / 178 (1.12%)	2 / 340 (0.59%)
occurrences (all)	8	2	2
Abnormal withdrawal bleeding			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Cervical polyp			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	2 / 340 (0.59%)
occurrences (all)	1	1	3
Vaginal haemorrhage			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	2	0	1
Menstruation irregular			
subjects affected / exposed	3 / 335 (0.90%)	1 / 178 (0.56%)	3 / 340 (0.88%)
occurrences (all)	3	1	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	2 / 335 (0.60%)	2 / 178 (1.12%)	3 / 340 (0.88%)
occurrences (all)	2	2	3
Bronchial hyperreactivity			
subjects affected / exposed	2 / 335 (0.60%)	1 / 178 (0.56%)	3 / 340 (0.88%)
occurrences (all)	2	1	3
Lung infiltration			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Nocturnal dyspnoea			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Obstructive airways disorder			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Oropharyngeal discomfort			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Rhinalgia			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Bronchial obstruction			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Bronchial secretion retention			
subjects affected / exposed	2 / 335 (0.60%)	2 / 178 (1.12%)	1 / 340 (0.29%)
occurrences (all)	2	2	1
Increased upper airway secretion			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	2 / 340 (0.59%)
occurrences (all)	1	1	2
Sneezing			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	3 / 340 (0.88%)
occurrences (all)	3	0	3
Nasal oedema			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	3 / 340 (0.88%)
occurrences (all)	1	1	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	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Tracheal disorder			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Tracheal inflammation			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	14 / 335 (4.18%)	5 / 178 (2.81%)	9 / 340 (2.65%)
occurrences (all)	16	5	9
Insomnia			
subjects affected / exposed	7 / 335 (2.09%)	9 / 178 (5.06%)	9 / 340 (2.65%)
occurrences (all)	7	12	10
Depressed mood			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	3 / 340 (0.88%)
occurrences (all)	1	0	3
Panic attack			
subjects affected / exposed	4 / 335 (1.19%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	4	1	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	1	0	1
Stress			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	2	0	0
Adjustment disorder			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Adjustment disorder with anxiety			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	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	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Somnambulism			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	7 / 335 (2.09%)	4 / 178 (2.25%)	8 / 340 (2.35%)
occurrences (all)	7	4	8
Product issues			
Device dislocation			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	1	0	1
Device occlusion			
subjects affected / exposed	4 / 335 (1.19%)	1 / 178 (0.56%)	2 / 340 (0.59%)
occurrences (all)	4	1	2
Device leakage			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Jaundice			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	1 / 335 (0.30%)	2 / 178 (1.12%)	0 / 340 (0.00%)
occurrences (all)	1	2	0
Biliary colic			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	3 / 340 (0.88%)
occurrences (all)	0	0	3
Hepatomegaly			

subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	2 / 340 (0.59%)
occurrences (all)	0	0	3
Cholecystitis chronic			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Hepatic pain			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	2
Hepatic steatosis			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Investigations			
Pulmonary function test decreased			
subjects affected / exposed	35 / 335 (10.45%)	23 / 178 (12.92%)	29 / 340 (8.53%)
occurrences (all)	42	28	35
Blood creatine phosphokinase increased			
subjects affected / exposed	26 / 335 (7.76%)	23 / 178 (12.92%)	23 / 340 (6.76%)
occurrences (all)	33	29	38
Forced expiratory volume decreased			
subjects affected / exposed	26 / 335 (7.76%)	12 / 178 (6.74%)	28 / 340 (8.24%)
occurrences (all)	31	13	31
Bacterial test positive			
subjects affected / exposed	29 / 335 (8.66%)	7 / 178 (3.93%)	30 / 340 (8.82%)
occurrences (all)	42	9	42
Alanine aminotransferase increased			
subjects affected / exposed	10 / 335 (2.99%)	14 / 178 (7.87%)	14 / 340 (4.12%)
occurrences (all)	12	15	18
Aspartate aminotransferase increased			
subjects affected / exposed	12 / 335 (3.58%)	13 / 178 (7.30%)	15 / 340 (4.41%)
occurrences (all)	13	14	20
Blood glucose decreased			
subjects affected / exposed	4 / 335 (1.19%)	1 / 178 (0.56%)	4 / 340 (1.18%)
occurrences (all)	4	1	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	2 / 335 (0.60%)	2 / 178 (1.12%)	1 / 340 (0.29%)
occurrences (all)	2	2	1
Clostridium test positive			
subjects affected / exposed	2 / 335 (0.60%)	1 / 178 (0.56%)	1 / 340 (0.29%)
occurrences (all)	2	1	1
Oxygen saturation decreased			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	2 / 340 (0.59%)
occurrences (all)	2	0	2
Transaminases increased			
subjects affected / exposed	2 / 335 (0.60%)	2 / 178 (1.12%)	1 / 340 (0.29%)
occurrences (all)	2	2	1
White blood cells urine positive			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	2 / 340 (0.59%)
occurrences (all)	3	0	3
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 335 (0.30%)	2 / 178 (1.12%)	1 / 340 (0.29%)
occurrences (all)	1	2	1
Blood bicarbonate decreased			
subjects affected / exposed	2 / 335 (0.60%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	2	1	0
Blood immunoglobulin E increased			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	1 / 340 (0.29%)
occurrences (all)	1	1	1
Body temperature increased			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	1	0	1
Crystal urine present			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	2	0	1
Haemoglobin decreased			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	2	0	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	0 / 335 (0.00%)	1 / 178 (0.56%)	1 / 340 (0.29%)
occurrences (all)	0	1	1
Monocyte count increased			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	1 / 340 (0.29%)
occurrences (all)	1	1	1
Pseudomonas test positive			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	1 / 340 (0.29%)
occurrences (all)	1	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	1 / 340 (0.29%)
occurrences (all)	0	1	1
Blood pressure increased			
subjects affected / exposed	0 / 335 (0.00%)	2 / 178 (1.12%)	0 / 340 (0.00%)
occurrences (all)	0	2	0
Candida test positive			
subjects affected / exposed	0 / 335 (0.00%)	2 / 178 (1.12%)	0 / 340 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Glucose tolerance test abnormal			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	1	0	1
Heart rate increased			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	2 / 340 (0.59%)
occurrences (all)	0	0	2
Human rhinovirus test positive			
subjects affected / exposed	2 / 335 (0.60%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	3	0	0
Influenza B virus test positive			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	2 / 340 (0.59%)
occurrences (all)	0	0	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			

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

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

Reticulocyte count increased			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Rubulavirus test positive			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Ultrasound liver abnormal			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Urine analysis abnormal			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Urine bilirubin increased			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Urine ketone body present			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Viral test positive			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Vitamin A decreased			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Vitamin E decreased			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	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	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Stoma site haemorrhage			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Stoma site pain			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Stoma site ulcer			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Stress fracture			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Upper limb fracture			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Thyroglossal cyst			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Cystic fibrosis related diabetes			
subjects affected / exposed	10 / 335 (2.99%)	10 / 178 (5.62%)	8 / 340 (2.35%)
occurrences (all)	10	10	8
Cystic fibrosis hepatic disease			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Cystic fibrosis lung			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	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	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	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

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

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

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

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			

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	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Stress urinary incontinence			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Nephrolithiasis			
subjects affected / exposed	3 / 335 (0.90%)	3 / 178 (1.69%)	2 / 340 (0.59%)
occurrences (all)	4	5	2
Acute kidney injury			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	2 / 340 (0.59%)
occurrences (all)	1	2	2
Dysuria			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	0
Chromaturia			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	1	0	1
Chronic kidney disease			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	1	0	1
Nocturia			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	0
Calculus urinary			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Glycosuria			
subjects affected / exposed	0 / 335 (0.00%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	0	1	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
Hypernatriuria			
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
Polyarthritis			
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	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Vaginitis bacterial			
subjects affected / exposed	1 / 335 (0.30%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	1	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	1 / 340 (0.29%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	11 / 335 (3.28%)	5 / 178 (2.81%)	16 / 340 (4.71%)
occurrences (all)	11	5	17
Decreased appetite			
subjects affected / exposed	12 / 335 (3.58%)	8 / 178 (4.49%)	6 / 340 (1.76%)
occurrences (all)	12	9	7
Hypoglycaemia			
subjects affected / exposed	5 / 335 (1.49%)	7 / 178 (3.93%)	3 / 340 (0.88%)
occurrences (all)	5	7	3
Hyperglycaemia			
subjects affected / exposed	7 / 335 (2.09%)	4 / 178 (2.25%)	3 / 340 (0.88%)
occurrences (all)	8	4	3
Iron deficiency			
subjects affected / exposed	6 / 335 (1.79%)	1 / 178 (0.56%)	3 / 340 (0.88%)
occurrences (all)	6	1	3
Glucose tolerance impaired			
subjects affected / exposed	3 / 335 (0.90%)	1 / 178 (0.56%)	2 / 340 (0.59%)
occurrences (all)	3	1	2
Dehydration			
subjects affected / exposed	1 / 335 (0.30%)	1 / 178 (0.56%)	3 / 340 (0.88%)
occurrences (all)	1	1	3
Hyponatraemia			
subjects affected / exposed	2 / 335 (0.60%)	1 / 178 (0.56%)	0 / 340 (0.00%)
occurrences (all)	2	1	0
Alcohol intolerance			
subjects affected / exposed	0 / 335 (0.00%)	0 / 178 (0.00%)	0 / 340 (0.00%)
occurrences (all)	0	0	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			

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

subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Investigations			
Pulmonary function test decreased			
subjects affected / exposed	15 / 176 (8.52%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	17	0	2
Blood creatine phosphokinase increased			
subjects affected / exposed	15 / 176 (8.52%)	0 / 19 (0.00%)	5 / 55 (9.09%)
occurrences (all)	18	0	5
Forced expiratory volume decreased			
subjects affected / exposed	15 / 176 (8.52%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	22	0	2
Bacterial test positive			
subjects affected / exposed	11 / 176 (6.25%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	15	0	2
Alanine aminotransferase increased			
subjects affected / exposed	15 / 176 (8.52%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	18	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	13 / 176 (7.39%)	0 / 19 (0.00%)	1 / 55 (1.82%)
occurrences (all)	14	0	1
Blood glucose decreased			
subjects affected / exposed	2 / 176 (1.14%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	2	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 176 (1.14%)	0 / 19 (0.00%)	1 / 55 (1.82%)
occurrences (all)	2	0	1
Weight decreased			
subjects affected / exposed	3 / 176 (1.70%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	3	0	2
Blood creatinine increased			
subjects affected / exposed	7 / 176 (3.98%)	0 / 19 (0.00%)	1 / 55 (1.82%)
occurrences (all)	8	0	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	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Blood cortisol decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Blood glucose fluctuation			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood magnesium increased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Blood testosterone decreased			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Blood testosterone increased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	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	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Urine bilirubin increased			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Urine ketone body present			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Viral test positive			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Vitamin A decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Vitamin E decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	3 / 176 (1.70%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	3	0	0
Procedural pain			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	6 / 176 (3.41%)	0 / 19 (0.00%)	2 / 55 (3.64%)
occurrences (all)	8	0	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			

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			

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			

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			

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

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

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			

subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	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			

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			

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			

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
Hypernatriuria			
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	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Infectious mononucleosis			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Mycobacterial disease carrier			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Superinfection bacterial			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Mycobacterium abscessus infection			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Oropharyngitis fungal			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Otitis externa fungal			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	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	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Bronchitis fungal			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis viral			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Erythema infectiosum			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Febrile infection			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis norovirus			
subjects affected / exposed	1 / 176 (0.57%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Genital herpes			
subjects affected / exposed	0 / 176 (0.00%)	0 / 19 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	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) Thrombosis subjects affected / exposed occurrences (all)	 0 / 60 (0.00%) 0 0 / 60 (0.00%) 0		
Surgical and medical procedures Ethmoid sinus surgery subjects affected / exposed occurrences (all) Wisdom teeth removal subjects affected / exposed occurrences (all)	 0 / 60 (0.00%) 0 0 / 60 (0.00%) 0		
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Pain subjects affected / exposed occurrences (all) Malaise subjects affected / exposed occurrences (all) Chest discomfort subjects affected / exposed occurrences (all) Chest pain subjects affected / exposed occurrences (all) Asthenia subjects affected / exposed occurrences (all) Chills	 8 / 60 (13.33%) 10 6 / 60 (10.00%) 6 1 / 60 (1.67%) 1 1 / 60 (1.67%) 1 0 / 60 (0.00%) 0 1 / 60 (1.67%) 1 1 / 60 (1.67%) 1		

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	0 / 60 (0.00%)			
occurrences (all)	0			
Painful respiration				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Throat irritation				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Nasal discharge discolouration				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Bronchiectasis				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Hypoxia				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
Paranasal sinus discomfort				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Bronchial hyperreactivity				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Lung infiltration				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Nocturnal dyspnoea				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Obstructive airways disorder				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Oropharyngeal discomfort				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	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	0 / 60 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Jaundice			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Cholelithiasis			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Biliary colic			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Hepatomegaly			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Cholecystitis chronic			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Hepatic pain			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Hepatic steatosis			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Investigations			
Pulmonary function test decreased			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	3		
Blood creatine phosphokinase increased			
subjects affected / exposed	10 / 60 (16.67%)		
occurrences (all)	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	1 / 60 (1.67%)			
occurrences (all)	1			
Atypical mycobacterium test positive				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Influenza A virus test positive				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Neutrophil count increased				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Gamma-glutamyltransferase increased				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
Blood magnesium decreased				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Clostridium test positive				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Oxygen saturation decreased				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Transaminases increased				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
White blood cells urine positive				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Activated partial thromboplastin time prolonged				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	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	0 / 60 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Thyroglossal cyst			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Cystic fibrosis related diabetes			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Cystic fibrosis hepatic disease			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Cystic fibrosis lung			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Dermoid cyst			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Naevus flammeus			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Cyanosis			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Palpitations			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	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			

Olfactory nerve disorder			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Disturbance in attention			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Eosinophilia			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Splenomegaly			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Bone marrow oedema			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Haemoconcentration			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Increased tendency to bruise			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	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	0 / 60 (0.00%)			
occurrences (all)	0			
Motion sickness				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Ototoxicity				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Tympanic membrane perforation				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Vestibular disorder				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Ear discomfort				
subjects affected / exposed	2 / 60 (3.33%)			
occurrences (all)	2			
Eye disorders				
Blepharospasm				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Conjunctivitis allergic				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Vision blurred				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Dry eye				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Eye pruritus				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	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			
Hypernatriuria				
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	0 / 60 (0.00%)			
occurrences (all)	0			
Superinfection bacterial				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Gastrointestinal viral infection				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Infective exacerbation of bronchiectasis				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Mycobacterium abscessus infection				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Oropharyngitis fungal				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	2			
Otitis externa fungal				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Parotitis				
subjects affected / exposed	1 / 60 (1.67%)			
occurrences (all)	1			
Vaginal infection				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Varicella				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	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	0 / 60 (0.00%)			
occurrences (all)	0			
Conjunctivitis viral				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Epididymitis				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Erythema infectiosum				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Febrile infection				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Genital herpes				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Genital herpes simplex				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Genital infection fungal				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	0 / 60 (0.00%)			
occurrences (all)	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	0 / 60 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Tooth infection			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Tracheobronchitis			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Trichomoniasis			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Upper respiratory fungal infection			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Vaginitis bacterial			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Vulvovaginitis			
subjects affected / exposed	0 / 60 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	1 / 60 (1.67%)		
occurrences (all)	1		
Decreased appetite			
subjects affected / exposed	3 / 60 (5.00%)		
occurrences (all)	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: