

**Clinical trial results:**

**A Phase III Randomized, Double-blind, Placebo-controlled, Multi-center Study in Adults to Determine the Safety and Efficacy of AZD7442, a Combination Product of Two Monoclonal Antibodies (AZD8895 and AZD1061), for Pre-exposure Prophylaxis of COVID-19**

**A Phase III Multi-center, Open-label Sub-study in Adults to Assess the Safety, PK, and Immunogenicity of Repeat Doses of AZD7442, a Combination Product of Two Monoclonal Antibodies (AZD8895 and AZD1061) (The PROVENT Repeat Dose Sub-study)**

**Summary**

EudraCT number	2020-004356-16
Trial protocol	GB BE FR
Global end of trial date	09 July 2024

**Results information**

Result version number	v1 (current)
This version publication date	22 December 2024
First version publication date	22 December 2024

**Trial information****Trial identification**

Sponsor protocol code	D8850C00002
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04625725
WHO universal trial number (UTN)	-

Notes:

**Sponsors**

Sponsor organisation name	AstraZeneca
Sponsor organisation address	151, 85, Södertälje, Sweden,
Public contact	Global Clinical Lead, AstraZeneca, 001 18772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, 001 18772409479, information.center@astrazeneca.com

Notes:

**Paediatric regulatory details**

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 March 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	09 July 2024
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

In the Main Study the efficacy objective was to estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of COVID-19 prior to Day 183; the safety objective was to assess the safety and tolerability of a single IM dose of AZD7442 compared to placebo.

In the Sub Study the main objective was to evaluate the safety and tolerability of repeat doses of AZD7442 300 mg and 600 mg IM

Protection of trial subjects:

The study was performed in compliance with International Council for Harmonisation (ICH) Good Clinical Practice, including the archiving of essential documents.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 November 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	United States: 3719
Country: Number of subjects enrolled	United Kingdom: 923
Country: Number of subjects enrolled	Belgium: 308
Country: Number of subjects enrolled	France: 182
Country: Number of subjects enrolled	Spain: 65
Worldwide total number of subjects	5197
EEA total number of subjects	555

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	3971
From 65 to 84 years	1206
85 years and over	20

## Subject disposition

### Recruitment

Recruitment details:

In the Main Study 5150 participants were planned to be randomized in a 2:1 ratio to receive a single IM dose of AZD7442 or saline placebo on Day 1 (approximately 3433 in the AZD7442 group and 1717 in the placebo). Approximately 500 eligible participants from the PROVENT Parent study were planned to be included in the Sub Study.

### Pre-assignment

Screening details:

Overall 5973 participants were screened in the Main Study

### Period 1

Period 1 title	Provent Main Study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	AZD7442

Arm description:

300 mg (AZD8895 and AZD1061)

Arm type	Experimental
Investigational medicinal product name	AZD7442
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A single dose of 300 mg of AZD7442 consisted of 2 sequential gluteal IM injections, one for each mAb component tixagevimab (AZD8895) and cilgavimab (AZD1061).

<b>Arm title</b>	Placebo
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Arm description:

Saline Placebo

Arm type	Placebo
Investigational medicinal product name	Placebo (saline 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose of 2 IM injections of 1.5 mL each

Number of subjects in period 1	AZD7442	Placebo
Started	3460	1737
Completed	2490	1179
Not completed	970	558
Adverse event, serious fatal	22	10
Physician decision	5	-
MISSING REASON	-	1
WITHDRAWAL OF CONSENT	3	2
PARTICIPANT DID NOT ATTEND VISIT	2	2
Consent withdrawn by subject	242	144
Adverse event, non-fatal	2	1
PARTICIPANT NOT COMPLIANT	1	1
INCARCERATION	3	-
PARTICIPANT NOT FULFILLING INCLUSION CRITERIA	1	-
MOVED ABROAD / LOCATION	7	2
Lost to follow-up	357	200
Participants dosed in sub-study	310	193
PARTICIPANT COULD NOT BE REACHED PRIOR TO DBL	14	2
Protocol deviation	1	-

## Period 2

Period 2 title	Provent Sub Study
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

## Arms

Are arms mutually exclusive?	Yes
Arm title	Group1

Arm description:

2 doses of AZD7442 300mg, 10-14 months schedule

Arm type	Experimental
Investigational medicinal product name	AZD7442
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses of AZD7442 300mg, 10-14 months schedule

A single dose of AZD7442 consisted of 2 sequential gluteal IM injections, one for each mAb component

<b>Arm title</b>	Group 2
Arm description: 2 doses of AZD7442 300mg, 6 month schedule	
Arm type	Experimental
Investigational medicinal product name	AZD7442
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 2 doses of AZD7442 300mg, 6 month schedule. A single dose of AZD7442 consisted of 2 sequential gluteal IM injections, one for each mAb component tixagevimab (AZD8895) and cilgavimab (AZD1061).	
<b>Arm title</b>	Group 3a
Arm description: 2 doses of AZD7442 300mg, 10-14 months schedule + 2 doses of AZD7442 600mg, 6 month schedule;	
Arm type	Experimental
Investigational medicinal product name	AZD7442
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 2 doses of AZD7442 300mg, 10-14 months schedule + 2 doses of AZD7442 600mg, 6 month schedule; A single dose of AZD7442 consisted of 2 sequential gluteal IM injections, one for each mAb component tixagevimab (AZD8895) and cilgavimab (AZD1061).	
<b>Arm title</b>	Group 3b
Arm description: 1 dose of AZD7442 300mg, 6 month schedule + 2 doses of AZD7442 600mg, 6 month schedule	
Arm type	Experimental
Investigational medicinal product name	AZD7442
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 1 dose of AZD7442 300mg, 6 month schedule + 2 doses of AZD7442 600mg, 6 month schedule. A single dose of AZD7442 consisted of 2 sequential gluteal IM injections, one for each mAb component tixagevimab (AZD8895) and cilgavimab (AZD1061).	

<b>Number of subjects in period 2<sup>[1]</sup></b>	Group1	Group 2	Group 3a
Started	234	119	76
Completed	194	90	64
Not completed	40	29	12
Adverse event, serious fatal	8	5	-
NON COMPLIANCE BY SUBJECT	-	-	-
Consent withdrawn by subject	11	13	5
SUBJECT MOVED OUT OF AREA	-	1	-
Adverse event, non-fatal	-	-	-
SUBJECT WAS MOVING AWAY	1	-	-
Lost to follow-up	20	10	6
SUBJECT'S DECLINING HEALTH	-	-	1

<b>Number of subjects in period 2<sup>[1]</sup></b>	Group 3b
Started	74
Completed	61
Not completed	13
Adverse event, serious fatal	1
NON COMPLIANCE BY SUBJECT	1
Consent withdrawn by subject	6
SUBJECT MOVED OUT OF AREA	-
Adverse event, non-fatal	1
SUBJECT WAS MOVING AWAY	-
Lost to follow-up	4
SUBJECT'S DECLINING HEALTH	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Only a subset of participants from Main study entered the Sub Study

## Baseline characteristics

### Reporting groups

Reporting group title	AZD7442
Reporting group description: 300 mg (AZD8895 and AZD1061)	
Reporting group title	Placebo
Reporting group description: Saline Placebo	

Reporting group values	AZD7442	Placebo	Total
Number of subjects	3460	1737	5197
Age Categorical			
For the Main Study FAS population is considered			
Units: Participants			
>= 18 - < 65 years	2643	1328	3971
>= 65 - < 85 years	805	401	1206
>= 85 years	12	8	20
Age Continuous			
Main Study: FAS population - Sub Study : As Treated			
Units: years			
arithmetic mean	53.65	53.27	
standard deviation	± 14.99	± 14.93	-
Sex: Female, Male			
Main Study: FAS population - Sub Study : As Treated			
Units: Participants			
Female	1594	802	2396
Male	1866	935	2801
Ethnicity			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Hispanic or Latino	539	215	754
Not Hispanic or Latino	2731	1412	4143
Not reported	116	72	188
Unknown	74	38	112
Race			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
White	2545	1249	3794
Black or African American	597	302	899
Asian	110	60	170
American Indian or Alaska Native	19	10	29
Native Hawaiian or Other Pacific Islander	4	4	8
Not reported	89	56	145
Unknown	79	42	121
Multiple	15	12	27
Missing	2	2	4
SARS-CoV-2 status at baseline			



Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Positive	19	6	25
Negative	3316	1665	4981
Missing	125	66	191
Region			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
North America	2487	1232	3719
United Kingdom	611	312	923
European Union	362	193	555
Any COVID-19 comorbidities at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Yes	2342	1206	3548
Missing	1118	531	1649
Any high risk for severe COVID-19 at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Yes	2674	1366	4040
Missing	786	371	1157
Height			
Main Study: FAS population - Sub Study : As Treated			
Units: cm			
arithmetic mean	170.04	170.17	
standard deviation	± 10.104	± 9.840	-
Baseline BMI			
Main Study: FAS population - Sub Study : As Treated			
Units: kg/m**2			
arithmetic mean	29.57	29.62	
standard deviation	± 6.878	± 6.984	-
Age Continuous			
Main Study: FAS population - Sub Study : As Treated			
Units: Years			
median	57	57	
full range (min-max)	18 to 98	18 to 99	-

### Subject analysis sets

Subject analysis set title	Group 1
Subject analysis set type	Safety analysis
Subject analysis set description: 2 doses of AZD7442 300mg, 10-14 months schedule	
Subject analysis set title	Group 2
Subject analysis set type	Safety analysis
Subject analysis set description: 2 doses of AZD7442 300mg, 6 month schedule	
Subject analysis set title	Group 3a
Subject analysis set type	Safety analysis
Subject analysis set description: 2 doses of AZD7442 300mg, 10-14 months schedule + 2 doses of AZD7442 600mg, 6 month schedule	

Subject analysis set title	Group 3b
Subject analysis set type	Safety analysis

Subject analysis set description:

1 dose of AZD7442 300mg, 6 month schedule + 2 doses of AZD7442 600mg, 6 month schedule

Reporting group values	Group 1	Group 2	Group 3a
Number of subjects	234	119	76
Age Categorical			
For the Main Study FAS population is considered			
Units: Participants			
>= 18 - < 65 years	145	72	60
>= 65 - < 85 years	89	47	15
>= 85 years	0	0	1
Age Continuous			
Main Study: FAS population - Sub Study : As Treated			
Units: years			
arithmetic mean	60.73	60.62	59.29
standard deviation	± 11.63	± 11.56	± 11.61
Sex: Female, Male			
Main Study: FAS population - Sub Study : As Treated			
Units: Participants			
Female	113	48	33
Male	121	71	43
Ethnicity			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Hispanic or Latino	31	6	9
Not Hispanic or Latino	192	109	61
Not reported	9	3	4
Unknown	2	1	2
Race			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
White	204	106	52
Black or African American	20	11	14
Asian	4	1	6
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Not reported	2	0	0
Unknown	4	1	4
Multiple	0	0	0
Missing	0	0	0
SARS-CoV-2 status at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Positive	0	1	0
Negative	229	114	75
Missing	5	4	1
Region			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			

North America	130	75	76
United Kingdom	77	27	0
European Union	27	17	0
Any COVID-19 comorbidities at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Yes	192	97	66
Missing	42	22	10
Any high risk for severe COVID-19 at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Yes	209	107	69
Missing	25	12	7
Height			
Main Study: FAS population - Sub Study : As Treated			
Units: cm			
arithmetic mean	170.03	171.25	169.03
standard deviation	± 10.29	± 10.06	± 9.76
Baseline BMI			
Main Study: FAS population - Sub Study : As Treated			
Units: kg/m**2			
arithmetic mean	29.44	29.21	29.24
standard deviation	± 6.21	± 6.44	± 6.61
Age Continuous			
Main Study: FAS population - Sub Study : As Treated			
Units: Years			
median	62	62	60.5
full range (min-max)	21 to 84	23 to 82	22 to 86
<b>Reporting group values</b>			
	Group 3b		
Number of subjects	74		
Age Categorical			
For the Main Study FAS population is considered			
Units: Participants			
>= 18 - < 65 years	53		
>= 65 - < 85 years	20		
>= 85 years	1		
Age Continuous			
Main Study: FAS population - Sub Study : As Treated			
Units: years			
arithmetic mean	59.00		
standard deviation	± 11.39		
Sex: Female, Male			
Main Study: FAS population - Sub Study : As Treated			
Units: Participants			
Female	35		
Male	39		
Ethnicity			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Hispanic or Latino	12		

Not Hispanic or Latino	56		
Not reported	4		
Unknown	2		
Race			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
White	53		
Black or African American	14		
Asian	1		
American Indian or Alaska Native	0		
Native Hawaiian or Other Pacific Islander	0		
Not reported	1		
Unknown	3		
Multiple	2		
Missing	0		
SARS-CoV-2 status at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Positive	1		
Negative	70		
Missing	3		
Region			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
North America	74		
United Kingdom	0		
European Union	0		
Any COVID-19 comorbidities at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Yes	68		
Missing	6		
Any high risk for severe COVID-19 at baseline			
Main Study: FAS population - Sub Study : As Treated			
Units: Subjects			
Yes	73		
Missing	1		
Height			
Main Study: FAS population - Sub Study : As Treated			
Units: cm			
arithmetic mean	168.72		
standard deviation	± 10.27		
Baseline BMI			
Main Study: FAS population - Sub Study : As Treated			
Units: kg/m**2			
arithmetic mean	31.65		
standard deviation	± 6.75		
Age Continuous			
Main Study: FAS population - Sub Study : As Treated			
Units: Years			

median	61		
full range (min-max)	30 to 92		


## End points

### End points reporting groups

Reporting group title	AZD7442
Reporting group description: 300 mg (AZD8895 and AZD1061)	
Reporting group title	Placebo
Reporting group description: Saline Placebo	
Reporting group title	Group1
Reporting group description: 2 doses of AZD7442 300mg, 10-14 months schedule	
Reporting group title	Group 2
Reporting group description: 2 doses ofAZD7442 300mg, 6 month schedule	
Reporting group title	Group 3a
Reporting group description: 2 doses of AZD7442 300mg, 10-14 months schedule + 2 doses of AZD7442 600mg, 6 month schedule;	
Reporting group title	Group 3b
Reporting group description: 1 dose of AZD7442 300mg, 6 month schedule + 2 doses of AZD7442 600mg, 6 month schedule	
Subject analysis set title	Group 1
Subject analysis set type	Safety analysis
Subject analysis set description: 2 doses of AZD7442 300mg, 10-14 months schedule	
Subject analysis set title	Group 2
Subject analysis set type	Safety analysis
Subject analysis set description: 2 doses ofAZD7442 300mg, 6 month schedule	
Subject analysis set title	Group 3a
Subject analysis set type	Safety analysis
Subject analysis set description: 2 doses of AZD7442 300mg, 10-14 months schedule + 2 doses of AZD7442 600mg, 6 month schedule	
Subject analysis set title	Group 3b
Subject analysis set type	Safety analysis
Subject analysis set description: 1 dose of AZD7442 300mg, 6 month schedule + 2 doses of AZD7442 600mg, 6 month schedule	

### Primary: Number of Participants with First case of SARS-CoV-2 RT-PCR-positive symptomatic illness

End point title	Number of Participants with First case of SARS-CoV-2 RT-PCR-positive symptomatic illness
End point description: To estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of COVID-19 prior to Day 183. Planned to be evaluated through Day 183, however, the number of events required for the primary endpoint was achieved 165 days after the study start date which is displayed in the primary efficacy row below. Final analysis is final data from the study based on the pre-planned 183 days of follow up for this endpoint.	
End point type	Primary
End point timeframe: 165 Days for primary analysis, 183 days for final analysis	

<b>End point values</b>	AZD7442	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3441	1731		
Units: Participants				
Primary Analysis	8	17		
Final Analysis	12	34		

## Statistical analyses

<b>Statistical analysis title</b>	Poisson Regression Model
Statistical analysis description:	
Primary Analysis	
Comparison groups	AZD7442 v Placebo
Number of subjects included in analysis	5172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression
Parameter estimate	Relative Risk Reduction
Point estimate	76.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.05
upper limit	89.96

<b>Statistical analysis title</b>	Poisson Regression Model
Statistical analysis description:	
Final Analysis	
Comparison groups	AZD7442 v Placebo
Number of subjects included in analysis	5172
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Poisson regression
Parameter estimate	Relative Risk Reduction
Point estimate	83.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	67.26
upper limit	91.21

**Secondary: The incidence of participants who have a post-treatment response (negative at baseline to positive at any time post-baseline) for SARS-CoV-2 nucleocapsid antibodies.**

End point title	The incidence of participants who have a post-treatment response (negative at baseline to positive at any time post-baseline) for SARS-CoV-2 nucleocapsid antibodies.
End point description:	To estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of SARS-CoV-2 infection
End point type	Secondary
End point timeframe:	366 days

End point values	AZD7442	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3121	1563		
Units: Participants				
SARS-CoV-2 Nucleocapsid Antibodies positive	198	139		

**Statistical analyses**

Statistical analysis title	Poisson Regression Model
Comparison groups	AZD7442 v Placebo
Number of subjects included in analysis	4684
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Poisson regression
Parameter estimate	Relative Risk Reduction
Point estimate	34.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.44
upper limit	46.05

**Secondary: Incidence of SARS-CoV-2 RT-PCR-positive severe or critical symptomatic illness occurring after dosing with IMP up to 366 days**

End point title	Incidence of SARS-CoV-2 RT-PCR-positive severe or critical symptomatic illness occurring after dosing with IMP up to 366 days
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End point description:

To estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of severe or critical symptomatic COVID-19

End point type	Secondary
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End point timeframe:

366 Days

End point values	AZD7442	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3441	1731		
Units: Participants				
Incidence	2	11		

### Statistical analyses

Statistical analysis title	Poisson Regression Model
Comparison groups	AZD7442 v Placebo
Number of subjects included in analysis	5172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Poisson regression
Parameter estimate	Relative Risk Reduction
Point estimate	91.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.31
upper limit	98.09

### Secondary: The incidence of COVID-19-related Emergency Department visits occurring after dosing with IMP by Day 366

End point title	The incidence of COVID-19-related Emergency Department visits occurring after dosing with IMP by Day 366
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End point description:

To estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of COVID-19-related Emergency Department visits

End point type	Secondary
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End point timeframe:

366 days

End point values	AZD7442	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3441	1731		
Units: Participants				
Incidence	8	8		

## Statistical analyses

Statistical analysis title	Poisson Regression Model
Comparison groups	AZD7442 v Placebo
Number of subjects included in analysis	5172
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.137
Method	Poisson regression
Parameter estimate	Relative Risk Reduction
Point estimate	52.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.61
upper limit	82.13

## Secondary: Serum AZD7442 concentrations, PK parameters if data permit.

End point title	Serum AZD7442 concentrations, PK parameters if data
End point description:	To assess the pharmacokinetics of AZD7442 administered as a single dose of 300 mg IM
End point type	Secondary
End point timeframe:	457 days

Notes:

[1] - 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: PK evaluation was done only for the AZD7442 treatment group.

End point values	AZD7442			
Subject group type	Reporting group			
Number of subjects analysed	3290			
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Day 8	18.667 (± 92.947)			
Day 29	22.602 (± 64.691)			
Day 58	18.707 (± 65.981)			

Day 92	14.037 (± 67.922)			
Day 183	5.593 (± 83.580)			
Day 366	1.340 (± 90.132)			
Day 457	0.565 (± 85.733)			

## Statistical analyses

No statistical analyses for this end point

## Secondary: Incidence of ADA to AZD7442 in serum

End point title	Incidence of ADA to AZD7442 in serum
End point description:	
To evaluate ADA responses to AZD7442 in serum	
End point type	Secondary
End point timeframe:	
457 days	

End point values	AZD7442	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3086	1540		
Units: Participants				
TE-ADA positive (ADA Incidence)	403	34		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until last study visit

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24.0
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### Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	AZD7442
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Reporting group description: -

Reporting group title	Group 2
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Reporting group description: -

Reporting group title	Group 1
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Reporting group description: -

Reporting group title	Group 3b
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Reporting group description: -

Reporting group title	Group 3a
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Reporting group description: -

Serious adverse events	Placebo	AZD7442	Group 2
Total subjects affected by serious adverse events			
subjects affected / exposed	97 / 1736 (5.59%)	215 / 3461 (6.21%)	20 / 119 (16.81%)
number of deaths (all causes)	10	22	5
number of deaths resulting from adverse events	10	22	5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Renal cell carcinoma			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Meningioma benign			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Adrenal gland cancer metastatic			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma recurrent			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Cholangiocarcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
External ear neoplasm malignant			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer metastatic			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Laryngeal cancer			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Pancreatic carcinoma recurrent			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Meningioma			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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 neoplasm malignant			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma recurrent			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Small cell lung cancer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Rectal cancer			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Rectal adenocarcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Tonsil cancer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage IV			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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 adenocarcinoma stage III			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 1736 (0.00%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (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
Hypertensive urgency			



subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Hypertensive crisis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Aortic aneurysm			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Shock haemorrhagic			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Secondary hypertension			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Withdrawal of life support			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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

General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Chest pain			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (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
Non-cardiac chest pain			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Sexual abuse			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Intermenstrual bleeding			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	2 / 119 (1.68%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Asthma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Aspiration			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 alkalosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Respiratory distress			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
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			
Suicidal ideation			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol abuse			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Bipolar disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Depression			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 decompensation			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Product issues			
Device deposit issue			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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			
Gallbladder obstruction			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Cholelithiasis			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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 acute			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hepatic failure			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hepatic cirrhosis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Investigations			
Troponin increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Multiple injuries			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Joint injury			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Incisional hernia, obstructive			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Gun shot wound			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Fibula fracture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Femur fracture			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Tendon rupture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Subdural haemorrhage			



subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Procedural pain			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Accidental overdose			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Femoral neck fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Foot fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Humerus fracture			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Patella fracture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal dialysis complication			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin abrasion			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Second degree chemical burn of skin			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Radius fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Congenital, familial and genetic disorders			
Congenital cystic kidney disease			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute left ventricular failure			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Acute myocardial infarction			
subjects affected / exposed	3 / 1736 (0.17%)	8 / 3461 (0.23%)	2 / 119 (1.68%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Paroxysmal atrioventricular block			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 1736 (0.06%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Angina pectoris			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Angina unstable			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arteriosclerosis coronary artery			

subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Atrial fibrillation			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Bradycardia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Atrioventricular block second degree			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 1736 (0.00%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Cardiac failure acute			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Coronary artery stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomegaly			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Cardiomyopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Coronary artery disease			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve disease			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Myocarditis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Ventricular arrhythmia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	2 / 119 (1.68%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complex regional pain syndrome			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bell's palsy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Carotid artery disease			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Carotid artery stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Cerebellar infarction			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Cerebral infarction			



subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Generalised tonic-clonic seizure			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Neuropathy peripheral			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Lumbar radiculopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Seizure			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Thalamic infarction			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Toxic encephalopathy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Anaemia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of chronic disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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			

Inner ear disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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			
Retinal detachment			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Abdominal pain			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Pancreatitis chronic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Pancreatitis acute			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (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
Mesenteric artery thrombosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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

Irritable bowel syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallstone ileus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Enterovesical fistula			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Diarrhoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Colitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Abdominal distension			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Haemorrhoids			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Gastritis			
subjects affected / exposed	3 / 1736 (0.17%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Melaena			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Oesophageal haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Overflow diarrhoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Salivary gland mass			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Small intestinal obstruction			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Peritoneal cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Pancreatitis relapsing			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Volvulus			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Vomiting			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Skin and subcutaneous tissue disorders			
Drug eruption			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			



Nephrolithiasis			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Acute kidney injury			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pelvi-ureteric obstruction			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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 kidney disease			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Subcapsular renal haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Urinary retention			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Thyrotoxic crisis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hypothyroidism			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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			
Osteoarthritis			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (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
Arthralgia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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

Ankylosing spondylitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Arthritis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Cervical spinal stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compartment syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Joint effusion			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Spondylolisthesis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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			
Diverticulitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Cystitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1736 (0.00%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Sepsis			
subjects affected / exposed	0 / 1736 (0.00%)	7 / 3461 (0.20%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Postoperative wound infection			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Peritonitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Abscess limb			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous graft site infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Bacteraemia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Enterococcal bacteraemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Endocarditis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Localised infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Influenza			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Incision site cellulitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Meningitis streptococcal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Necrotising fasciitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Pneumococcal bacteraemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 1736 (0.00%)	7 / 3461 (0.20%)	3 / 119 (2.52%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia bacterial			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 fungal			



subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Tonsillitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	2 / 119 (1.68%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Secondary syphilis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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 diarrhoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Vestibular neuronitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Urosepsis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
COVID-19 pneumonia			
subjects affected / exposed	20 / 1736 (1.15%)	4 / 3461 (0.12%)	3 / 119 (2.52%)
occurrences causally related to treatment / all	0 / 20	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	6 / 1736 (0.35%)	2 / 3461 (0.06%)	2 / 119 (1.68%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hyperglycaemia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (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
Diabetes with hyperosmolarity			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Alcoholic ketoacidosis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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
Diabetes mellitus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Diabetic ketoacidosis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (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
Hypertriglyceridaemia			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hypocalcaemia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (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 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hypokalaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Hyponatraemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (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
Metabolic acidosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
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	Group 1	Group 3b	Group 3a
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 234 (13.25%)	12 / 74 (16.22%)	12 / 76 (15.79%)
number of deaths (all causes)	8	1	0
number of deaths resulting from adverse events	8	1	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Renal cell carcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal gland cancer metastatic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma recurrent			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 myeloid leukaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

External ear neoplasm malignant subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer metastatic subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma recurrent subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic squamous cell carcinoma subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 neoplasm malignant			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma recurrent			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsil cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage IV			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			



subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Hypertensive urgency			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Deep vein thrombosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Secondary hypertension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Withdrawal of life support			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oedema peripheral subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Sexual abuse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermenstrual bleeding			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Acute pulmonary oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	3 / 234 (1.28%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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 alkalosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Pneumothorax			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol abuse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Mental status changes			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device deposit issue			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Hepatobiliary disorders			
Gallbladder obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 obstruction			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 acute			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatic cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Troponin increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 pressure increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			

Concussion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia, obstructive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Overdose			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal dialysis complication			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 laceration			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 abrasion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Second degree chemical burn of skin			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Radius fracture			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Sternal fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Congenital cystic kidney disease			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac disorders			
Acute left ventricular failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Paroxysmal atrioventricular block			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Angina pectoris			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina unstable			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Arrhythmia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardio-respiratory arrest			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomegaly			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 arrhythmia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Transient ischaemic attack			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Metabolic encephalopathy			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (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
Complex regional pain syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (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
Bell's palsy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous sinus thrombosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Lacunar infarction			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Simple partial seizures			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Leukocytosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of chronic disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Inner ear disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Retinal detachment			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
Abdominal hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 ulcer haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 chronic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis acute			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Mesenteric artery thrombosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallstone ileus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 haemorrhagic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 distension			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Ileus paralytic			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Ileus			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Hiatus hernia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Haemorrhoids			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Pancreatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overflow diarrhoea			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 relapsing			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Diabetic foot			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 kidney injury			
subjects affected / exposed	2 / 234 (0.85%)	2 / 74 (2.70%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 kidney disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			

subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Haematuria			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
End stage renal disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Endocrine disorders			
Thyrotoxic crisis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Costochondritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankylosing spondylitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Back pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Cervical spinal stenosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Compartment syndrome			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 spinal stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (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
Postoperative wound infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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 abscess			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Appendicitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous graft site infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal bacteraemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			

subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Catheter site infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Incision site cellulitis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis streptococcal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 viral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal bacteraemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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			



subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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 fungal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 pneumococcal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Secondary syphilis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Urinary tract infection			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Wound infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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 diarrhoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (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
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes with hyperosmolarity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic ketoacidosis			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Diabetes mellitus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (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
Hypertriglyceridaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
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 2 diabetes mellitus			

subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Placebo	AZD7442	Group 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	993 / 1736 (57.20%)	1988 / 3461 (57.44%)	94 / 119 (78.99%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Basal cell carcinoma			
subjects affected / exposed	5 / 1736 (0.29%)	8 / 3461 (0.23%)	2 / 119 (1.68%)
occurrences (all)	6	8	2
Malignant melanoma			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Benign neoplasm of skin			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Blepharal papilloma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Eyelid tumour			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lipoma			
subjects affected / exposed	0 / 1736 (0.00%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Benign breast neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Malignant melanoma in situ			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Melanocytic naevus			
subjects affected / exposed	1 / 1736 (0.06%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	1	8	0
Prostate cancer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Seborrhoeic keratosis			
subjects affected / exposed	3 / 1736 (0.17%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	3	8	0
Skin papilloma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Uterine leiomyoma			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Abdominal wall neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Benign hepatic neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Benign salivary gland neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Bowen's disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cancer fatigue			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Colon adenoma			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Colon cancer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Essential thrombocythaemia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Fibroma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Haemangioma			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Haemangioma of bone			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hair follicle tumour benign			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Dysplastic naevus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Neoplasm malignant			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Neoplasm skin			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0

Leiomyoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lung neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Nasal cavity cancer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Meningioma			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Metastases to liver			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Metastases to lymph nodes			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Metastatic squamous cell carcinoma			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Naevus haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Malignant neoplasm of eyelid			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Papilloma			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Parathyroid tumour benign			



subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Plasma cell myeloma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Plasma cell myeloma recurrent			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Salivary gland cancer			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Skin cancer			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	2 / 119 (1.68%)
occurrences (all)	0	2	3
Thyroid cancer			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Tongue neoplasm benign			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Spinal cord neoplasm			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Arteriovenous fistula			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0

Deep vein thrombosis			
subjects affected / exposed	3 / 1736 (0.17%)	8 / 3461 (0.23%)	1 / 119 (0.84%)
occurrences (all)	4	9	1
Essential hypertension			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	1	5	0
Arteriosclerosis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Aortic dilatation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Hot flush			
subjects affected / exposed	2 / 1736 (0.12%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	2	10	0
Hypertension			
subjects affected / exposed	56 / 1736 (3.23%)	99 / 3461 (2.86%)	7 / 119 (5.88%)
occurrences (all)	60	102	9
Hypotension			
subjects affected / exposed	5 / 1736 (0.29%)	10 / 3461 (0.29%)	1 / 119 (0.84%)
occurrences (all)	5	10	1
Venous thrombosis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Thrombophlebitis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

Thrombophlebitis superficial subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Varicose vein subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Orthostatic hypotension subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	1 / 119 (0.84%) 1
Venous thrombosis limb subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
White coat hypertension subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Angiodysplasia subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Aortic aneurysm subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Aortic stenosis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 3	0 / 119 (0.00%) 0
Blood pressure fluctuation subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	1 / 119 (0.84%) 1
Blood pressure inadequately controlled subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Circulatory collapse			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypertensive emergency			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypertensive urgency			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Intermittent claudication			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Lymphoedema			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Neurogenic shock			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypertensive crisis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Peripheral venous disease			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Raynaud's phenomenon			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Shock haemorrhagic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Thrombosis			

subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	1 / 119 (0.84%) 1
Vascular pain subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Pregnancy, puerperium and perinatal conditions Haemorrhage in pregnancy subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	14 / 1736 (0.81%) 14	19 / 3461 (0.55%) 20	1 / 119 (0.84%) 1
Axillary pain subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	7 / 1736 (0.40%) 8	9 / 3461 (0.26%) 10	0 / 119 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	166 / 1736 (9.56%) 201	369 / 3461 (10.66%) 439	33 / 119 (27.73%) 49
Chills subjects affected / exposed occurrences (all)	72 / 1736 (4.15%) 79	155 / 3461 (4.48%) 169	17 / 119 (14.29%) 22
Chronic fatigue syndrome subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Energy increased subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Facial discomfort subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Chest pain			

subjects affected / exposed	1 / 1736 (0.06%)	9 / 3461 (0.26%)	1 / 119 (0.84%)
occurrences (all)	1	9	1
Feeling cold			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Feeling hot			
subjects affected / exposed	3 / 1736 (0.17%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	3	2	0
Feeling jittery			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Inflammation			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Influenza like illness			
subjects affected / exposed	14 / 1736 (0.81%)	27 / 3461 (0.78%)	4 / 119 (3.36%)
occurrences (all)	16	29	11
Injection site bruising			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Injection site discomfort			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Injection site erythema			
subjects affected / exposed	2 / 1736 (0.12%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	2	9	0
Injection site haematoma			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Injection site haemorrhage			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Injection site induration			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Injection site joint pain			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Injection site mass			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Injection site oedema			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Injection site pain			
subjects affected / exposed	19 / 1736 (1.09%)	37 / 3461 (1.07%)	1 / 119 (0.84%)
occurrences (all)	20	39	1
Injection site paraesthesia			
subjects affected / exposed	4 / 1736 (0.23%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	4	3	0
Injection site pruritus			
subjects affected / exposed	2 / 1736 (0.12%)	9 / 3461 (0.26%)	1 / 119 (0.84%)
occurrences (all)	2	9	1
Malaise			
subjects affected / exposed	10 / 1736 (0.58%)	46 / 3461 (1.33%)	4 / 119 (3.36%)
occurrences (all)	10	46	4
Injection site reaction			
subjects affected / exposed	4 / 1736 (0.23%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences (all)	4	7	0
Injection site swelling			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	2	4	1
Injection site urticaria			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Injection site warmth			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Injury associated with device			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Injection site rash			

subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Medical device site irritation			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	6 / 1736 (0.35%)	14 / 3461 (0.40%)	3 / 119 (2.52%)
occurrences (all)	6	14	3
Oedema			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	8 / 1736 (0.46%)	17 / 3461 (0.49%)	1 / 119 (0.84%)
occurrences (all)	9	18	1
Pain			
subjects affected / exposed	79 / 1736 (4.55%)	185 / 3461 (5.35%)	19 / 119 (15.97%)
occurrences (all)	82	212	20
Vaccination site erythema			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	77 / 1736 (4.44%)	150 / 3461 (4.33%)	15 / 119 (12.61%)
occurrences (all)	84	158	17
Sensation of foreign body			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	2	3	1
Vaccination site discomfort			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	10 / 1736 (0.58%)	15 / 3461 (0.43%)	0 / 119 (0.00%)
occurrences (all)	10	16	0
Vessel puncture site haematoma			



subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vaccination site mass			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	4	8	0
Vaccination site reaction			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Feeling abnormal			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Catheter site swelling			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Crepitations			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cyst			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Facial pain			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Adverse drug reaction			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Foaming at mouth			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	3	3	1
Generalised oedema			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hangover			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hernia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Mass			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Puncture site pruritus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Retention cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Secretion discharge			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0

Puncture site oedema subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Immune system disorders			
Allergy to arthropod bite subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Anaphylactic reaction subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Drug hypersensitivity subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Allergy to chemicals subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	4 / 1736 (0.23%) 4	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	11 / 1736 (0.63%) 11	29 / 3461 (0.84%) 29	2 / 119 (1.68%) 2
Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Allergy to plants subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Primary amyloidosis			

subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Sarcoidosis subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Mite allergy subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 2	0 / 119 (0.00%) 0
Social circumstances			
Physical abuse subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Physical assault subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Alcohol use subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Menopause subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Reproductive system and breast disorders			
Breast cyst subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Abnormal uterine bleeding subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	9 / 3461 (0.26%) 9	0 / 119 (0.00%) 0
Breast mass subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Breast swelling			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Dysmenorrhoea			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Ejaculation failure			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Pelvic pain			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Intermenstrual bleeding			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Menometrorrhagia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Menopausal disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Menopausal symptoms			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Pelvic adhesions			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Heavy menstrual bleeding			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Perineal pain			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Polycystic ovaries			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Priapism			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Prostatitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Uterine polyp			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Vulva cyst			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Uterine prolapse			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Balanoposthitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Adenomyosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Atrophic vulvovaginitis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Bartholin's cyst			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Breast calcifications			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Breast enlargement			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Breast pain			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Cervical dysplasia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Cervix inflammation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oligomenorrhoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Epididymal cyst			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Fibrocystic breast disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gynaecomastia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Menstruation irregular			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Nipple pain			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Endometrial hyperplasia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Ovarian cyst			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Pelvic congestion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Peyronie's disease			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Premenstrual syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Prostatomegaly			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	1	3	1
Testicular cyst			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Testicular pain			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Urogenital atrophy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vaginal cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vaginal prolapse			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Varicocele			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Vulvovaginal inflammation			



subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Vulvovaginal pruritus subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Asthma subjects affected / exposed occurrences (all)	8 / 1736 (0.46%) 9	19 / 3461 (0.55%) 22	1 / 119 (0.84%) 1
Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	8 / 1736 (0.46%) 14	19 / 3461 (0.55%) 22	2 / 119 (1.68%) 3
Choking subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Bronchospasm subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Bronchitis chronic subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Bronchiectasis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Atelectasis subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	4 / 3461 (0.12%) 4	1 / 119 (0.84%) 1
Cough subjects affected / exposed occurrences (all)	179 / 1736 (10.31%) 213	423 / 3461 (12.22%) 517	36 / 119 (30.25%) 58
Dry throat subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	1 / 119 (0.84%) 1
Dysphonia			

subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	4	8	0
Dyspnoea			
subjects affected / exposed	67 / 1736 (3.86%)	162 / 3461 (4.68%)	18 / 119 (15.13%)
occurrences (all)	92	225	29
Dyspnoea exertional			
subjects affected / exposed	2 / 1736 (0.12%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	2	10	0
Epistaxis			
subjects affected / exposed	6 / 1736 (0.35%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	6	8	0
Haemoptysis			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Hypoxia			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Nasal obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Nasal discomfort			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	114 / 1736 (6.57%)	283 / 3461 (8.18%)	26 / 119 (21.85%)
occurrences (all)	128	320	34
Nasal cavity mass			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasal pruritus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus discomfort			

subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Pharyngeal erythema			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Pharyngeal swelling			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Pleural effusion			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Pleurisy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	9 / 1736 (0.52%)	19 / 3461 (0.55%)	2 / 119 (1.68%)
occurrences (all)	10	19	2
Oropharyngeal discomfort			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	117 / 1736 (6.74%)	305 / 3461 (8.81%)	21 / 119 (17.65%)
occurrences (all)	134	357	34
Rhinitis allergic			
subjects affected / exposed	5 / 1736 (0.29%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	5	10	0
Respiratory tract congestion			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Pulmonary mass			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	2	1	1
Pulmonary fibrosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			

subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	1 / 119 (0.84%)
occurrences (all)	2	5	1
Pulmonary congestion			
subjects affected / exposed	8 / 1736 (0.46%)	25 / 3461 (0.72%)	3 / 119 (2.52%)
occurrences (all)	8	26	4
Rhinorrhoea			
subjects affected / exposed	124 / 1736 (7.14%)	316 / 3461 (9.13%)	29 / 119 (24.37%)
occurrences (all)	141	363	40
Sinonasal obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	0	3	1
Sinus congestion			
subjects affected / exposed	15 / 1736 (0.86%)	38 / 3461 (1.10%)	2 / 119 (1.68%)
occurrences (all)	20	45	2
Sinus pain			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Sleep apnoea syndrome			
subjects affected / exposed	4 / 1736 (0.23%)	5 / 3461 (0.14%)	3 / 119 (2.52%)
occurrences (all)	4	5	3
Sneezing			
subjects affected / exposed	11 / 1736 (0.63%)	21 / 3461 (0.61%)	2 / 119 (1.68%)
occurrences (all)	11	24	2
Suffocation feeling			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	1	7	0
Wheezing			
subjects affected / exposed	9 / 1736 (0.52%)	15 / 3461 (0.43%)	0 / 119 (0.00%)
occurrences (all)	9	16	0
Vasomotor rhinitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			

subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Acute respiratory failure			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	2	4	1
Allergic bronchitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Aspiration			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Increased viscosity of bronchial secretion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Asthmatic crisis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Catarrh			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Emphysema			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Hiccups			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Increased bronchial secretion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Asthma exercise induced			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Laryngeal leukoplakia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0

Laryngeal oedema			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Laryngitis allergic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lung consolidation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lung disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal plaque			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasal oedema			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasal ulcer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Obstructive airways disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Nasal inflammation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Orthopnoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Pharyngeal hypertrophy subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Pleuritic pain subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Pneumonia aspiration subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Pneumonitis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
Pulmonary artery dilatation subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Respiratory distress subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Pulmonary oedema subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Pulmonary toxicity subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Rales subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Reflux laryngitis subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	1 / 3461 (0.03%) 1	1 / 119 (0.84%) 1
Respiratory arrest subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Pulmonary hypertension subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0

Respiratory failure subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Respiratory gas exchange disorder subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Rhonchi subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
Sputum discoloured subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Tachypnoea subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	1 / 119 (0.84%) 1
Throat tightness subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
Tonsillar hypertrophy subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Tracheal disorder subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Upper respiratory tract congestion subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Vocal cord polyp subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Tonsillar erythema subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Psychiatric disorders Anxiety			



subjects affected / exposed	11 / 1736 (0.63%)	34 / 3461 (0.98%)	2 / 119 (1.68%)
occurrences (all)	11	36	2
Abnormal dreams			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Aggression			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Anxiety disorder			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	1	4	1
Confusional state			
subjects affected / exposed	9 / 1736 (0.52%)	15 / 3461 (0.43%)	2 / 119 (1.68%)
occurrences (all)	9	15	2
Depressed mood			
subjects affected / exposed	4 / 1736 (0.23%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	4	7	0
Depression			
subjects affected / exposed	8 / 1736 (0.46%)	22 / 3461 (0.64%)	3 / 119 (2.52%)
occurrences (all)	8	22	3
Obsessive-compulsive disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Euphoric mood			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	14 / 1736 (0.81%)	21 / 3461 (0.61%)	1 / 119 (0.84%)
occurrences (all)	14	22	1
Irritability			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

Mixed anxiety and depressive disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Nightmare			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Disorientation			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Post-traumatic stress disorder			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	1	1
Restlessness			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Somatic symptom disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Suicidal ideation			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Sleep disorder			
subjects affected / exposed	3 / 1736 (0.17%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	3	7	0
Autism spectrum disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Anger			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Alcoholism			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Alcohol abuse			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Bipolar disorder			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Borderline personality disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Claustrophobia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Drug abuse			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Drug use disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Acute stress disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Generalised anxiety disorder			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Grief reaction			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Hallucinations, mixed			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Mania			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Mental status changes			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Panic disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Persistent complex bereavement disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Rapid eye movement sleep behaviour disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Sleep terror			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Product issues			
Device malfunction			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Device occlusion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Device loosening			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Device breakage			

subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Device physical property issue subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cholecystitis			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Cholelithiasis			
subjects affected / exposed	5 / 1736 (0.29%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	5	7	0
Hepatic steatosis			
subjects affected / exposed	7 / 1736 (0.40%)	11 / 3461 (0.32%)	2 / 119 (1.68%)
occurrences (all)	7	11	2
Nonalcoholic fatty liver disease			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Hepatic fibrosis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Cholecystitis chronic			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Bile duct stone			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Biliary dyskinesia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Hepatic cirrhosis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Hepatic cyst subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Hepatic cytolysis subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Hepatobiliary cyst subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Hepatosplenomegaly subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Hyperplastic cholecystopathy subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Non-alcoholic steatohepatitis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Portal vein thrombosis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 2	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Investigations			
Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	4 / 3461 (0.12%) 4	0 / 119 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Alanine aminotransferase increased			

subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	1 / 119 (0.84%)
occurrences (all)	4	8	1
Bacterial test positive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	17 / 1736 (0.98%)	24 / 3461 (0.69%)	0 / 119 (0.00%)
occurrences (all)	17	24	0
Blood cholesterol increased			
subjects affected / exposed	3 / 1736 (0.17%)	9 / 3461 (0.26%)	2 / 119 (1.68%)
occurrences (all)	3	9	2
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Blood creatinine increased			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	2	6	0
Blood glucose fluctuation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Blood glucose increased			
subjects affected / exposed	9 / 1736 (0.52%)	17 / 3461 (0.49%)	1 / 119 (0.84%)
occurrences (all)	9	17	1
Blood potassium decreased			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Blood potassium increased			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Blood pressure diastolic increased			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Blood pressure increased			
subjects affected / exposed	8 / 1736 (0.46%)	16 / 3461 (0.46%)	0 / 119 (0.00%)
occurrences (all)	8	16	0

Blood pressure systolic increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Blood testosterone decreased subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	4 / 3461 (0.12%) 4	0 / 119 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
C-reactive protein increased subjects affected / exposed occurrences (all)	9 / 1736 (0.52%) 9	16 / 3461 (0.46%) 16	2 / 119 (1.68%) 2
Coagulation test abnormal subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Cardiac murmur subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	2 / 3461 (0.06%) 2	1 / 119 (0.84%) 1
Cortisol decreased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Gamma-glutamyltransferase increased			



subjects affected / exposed	2 / 1736 (0.12%)	12 / 3461 (0.35%)	1 / 119 (0.84%)
occurrences (all)	2	12	1
Electrocardiogram abnormal			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Haemoglobin decreased			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Heart rate increased			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Hepatic enzyme increased			
subjects affected / exposed	9 / 1736 (0.52%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences (all)	9	6	0
International normalised ratio increased			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	2	5	0
International normalised ratio abnormal			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Liver function test abnormal			
subjects affected / exposed	1 / 1736 (0.06%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences (all)	1	6	1
Liver function test increased			
subjects affected / exposed	8 / 1736 (0.46%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	8	9	0
Monocyte count increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Mean cell volume decreased			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Platelet count decreased			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Platelet count increased			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	0	3	1
Protein urine present			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Prothrombin level increased			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Red blood cell count increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Red blood cells urine positive			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Smear cervix abnormal			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Serum ferritin decreased			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Reticulocyte count decreased			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Respiratory rate decreased			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	3 / 1736 (0.17%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	3	2	0
Troponin increased			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Urine analysis abnormal			
subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	4	8	0
Weight increased			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
White blood cell count increased			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
White blood cells urine positive			
subjects affected / exposed	5 / 1736 (0.29%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	5	11	0
Aortic bruit			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Blood calcium increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Blood folate decreased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase abnormal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Blood sodium increased			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Coagulation factor increased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Chlamydia test positive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Carbohydrate antigen 19-9 increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Brain natriuretic peptide increased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Blood thrombin increased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Blood glucose abnormal			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Blood iron decreased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Body temperature decreased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1

Lipids increased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Laboratory test abnormal			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Haematocrit increased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Glucose urine present			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Culture urine positive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Crystal urine present			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Mycoplasma test positive			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Creatinine renal clearance increased			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Norovirus test positive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Neisseria test positive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Weight decreased			
subjects affected / exposed	3 / 1736 (0.17%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	3	1	0
Urine output decreased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Urinary casts			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Transferrin saturation increased			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Reticulocyte count increased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Respiratory rate increased subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
White blood cells urine subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
HIV test positive subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Fibrin D dimer increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	1 / 119 (0.84%) 1
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Electrocardiogram T wave amplitude decreased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Electrocardiogram T wave abnormal subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Electrocardiogram P wave biphasic subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
ECG signs of ventricular hypertrophy subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Coagulation factor VIII level increased			

subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Blood HIV RNA increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Anti factor VIII antibody increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Vitamin B12 decreased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Vitamin B1 decreased subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Troponin I increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
Thrombin-antithrombin III complex increased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
SARS-CoV-2 test positive subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
QRS axis abnormal subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Vitamin D decreased subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	1 / 119 (0.84%) 1
Injury, poisoning and procedural complications			
Anaesthetic complication subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Abdominal injury			



subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Animal bite			
subjects affected / exposed	4 / 1736 (0.23%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	4	2	0
Arteriovenous fistula site complication			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	2 / 1736 (0.12%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	2	10	0
Arthropod sting			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Back injury			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Complications of transplant surgery			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cartilage injury			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Chest injury			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Arteriovenous fistula aneurysm			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Ankle fracture			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Bone contusion			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

Contusion			
subjects affected / exposed	4 / 1736 (0.23%)	22 / 3461 (0.64%)	2 / 119 (1.68%)
occurrences (all)	4	24	2
Epicondylitis			
subjects affected / exposed	4 / 1736 (0.23%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences (all)	4	6	0
Eyelid contusion			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Face injury			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	1	1
Foreign body in eye			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Femur fracture			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Foot fracture			
subjects affected / exposed	3 / 1736 (0.17%)	15 / 3461 (0.43%)	1 / 119 (0.84%)
occurrences (all)	3	15	1
Foreign body			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Foreign body in ear			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	17 / 1736 (0.98%)	44 / 3461 (1.27%)	7 / 119 (5.88%)
occurrences (all)	17	44	7
Hand fracture			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	2	4	1
Head injury			
subjects affected / exposed	1 / 1736 (0.06%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	1	10	0

Hip fracture			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Injection related reaction			
subjects affected / exposed	6 / 1736 (0.35%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	6	13	0
Joint injury			
subjects affected / exposed	8 / 1736 (0.46%)	6 / 3461 (0.17%)	2 / 119 (1.68%)
occurrences (all)	8	6	2
Lumbar vertebral fracture			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Ligament sprain			
subjects affected / exposed	6 / 1736 (0.35%)	18 / 3461 (0.52%)	1 / 119 (0.84%)
occurrences (all)	6	18	1
Limb injury			
subjects affected / exposed	9 / 1736 (0.52%)	11 / 3461 (0.32%)	2 / 119 (1.68%)
occurrences (all)	9	11	2
Lip injury			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Lower limb fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ligament rupture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Meniscus injury			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Muscle rupture			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Muscle strain			
subjects affected / exposed	3 / 1736 (0.17%)	8 / 3461 (0.23%)	1 / 119 (0.84%)
occurrences (all)	3	8	1

Neck injury			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Patella fracture			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Rib fracture			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Periorbital haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Post-traumatic pain			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Procedural pain			
subjects affected / exposed	10 / 1736 (0.58%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	11	11	0
Radius fracture			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Pelvic bone injury			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Road traffic accident			
subjects affected / exposed	4 / 1736 (0.23%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences (all)	4	6	0
Skin abrasion			
subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	1 / 119 (0.84%)
occurrences (all)	4	10	1
Skin laceration			
subjects affected / exposed	7 / 1736 (0.40%)	22 / 3461 (0.64%)	0 / 119 (0.00%)
occurrences (all)	7	25	0
Skull fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Splinter			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Upper limb fracture			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Stress fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tendon rupture			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	3	3	0
Thermal burn			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Tooth fracture			
subjects affected / exposed	0 / 1736 (0.00%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	0	7	0
Traumatic haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vaccination complication			
subjects affected / exposed	50 / 1736 (2.88%)	71 / 3461 (2.05%)	0 / 119 (0.00%)
occurrences (all)	81	132	0
Vascular access site haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Wrist fracture			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Chemical burns of eye			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

Accident at work			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Alcohol poisoning			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Arteriovenous fistula occlusion			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Avulsion fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Barotitis media			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Accident			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Haemodialysis complication			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Heat exhaustion			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	3	3	1
Corneal abrasion			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Craniocerebral injury			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Gun shot wound			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Eye injury			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Facial bones fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Fibula fracture			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Graft complication			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Extradural haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Humerus fracture			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Hyphaema			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Incisional hernia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Injury			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Joint dislocation			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	2	3	1
Ligament injury			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Poisoning			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Multiple fractures			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Muscle injury			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nerve injury			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Osteochondral fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Overdose			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Median nerve injury			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	2
Post concussion syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Post procedural complication			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Post procedural constipation			



subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Post procedural diarrhoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Post-traumatic neck syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Postoperative delirium			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Spinal column injury			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Radiation pneumonitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Second degree chemical burn of skin			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Seroma			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Skin injury			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Skin wound			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Procedural nausea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Stab wound			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Stomal hernia			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Subdural haematoma			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Sunburn			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tendon injury			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Tibia fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Traumatic ulcer			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ulnar nerve injury			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	2
Vulvovaginal injury			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Arteriovenous malformation			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Thalassaemia beta			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Dermoid cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Type V hyperlipidaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Angina unstable			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Angina pectoris			
subjects affected / exposed	4 / 1736 (0.23%)	10 / 3461 (0.29%)	3 / 119 (2.52%)
occurrences (all)	4	10	3
Atrial fibrillation			
subjects affected / exposed	6 / 1736 (0.35%)	13 / 3461 (0.38%)	3 / 119 (2.52%)
occurrences (all)	6	13	3
Bradycardia			
subjects affected / exposed	5 / 1736 (0.29%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	5	4	1
Bundle branch block left			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Ischaemic cardiomyopathy			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Coronary artery disease			
subjects affected / exposed	0 / 1736 (0.00%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences (all)	0	6	1
Cardiomyopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	10 / 1736 (0.58%)	17 / 3461 (0.49%)	0 / 119 (0.00%)
occurrences (all)	10	21	0
Left ventricular failure			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Sinus arrhythmia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Tachycardia			
subjects affected / exposed	5 / 1736 (0.29%)	11 / 3461 (0.32%)	0 / 119 (0.00%)
occurrences (all)	5	11	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	2 / 119 (1.68%)
occurrences (all)	0	3	2
Atrioventricular block first degree			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	0	3	1
Atrial flutter			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Atrial enlargement			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Arteriosclerosis coronary artery			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Arrhythmia supraventricular			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Aortic valve stenosis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Aortic valve sclerosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Acute myocardial infarction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Acute left ventricular failure			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Acute coronary syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Cardiac failure acute			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Cardiomegaly			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Chronotropic incompetence			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Diastolic dysfunction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Coronary artery stenosis			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Bundle branch block right			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Bifascicular block			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Cardiac failure			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Coronary artery occlusion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Extrasystoles			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Intracardiac thrombus			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Left atrial enlargement			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Left ventricular dysfunction			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Left ventricular hypertrophy			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Mitral valve incompetence			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Mitral valve stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Myocardial infarction			

subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Ventricular tachycardia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ventricular hypokinesia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ventricular hypertrophy			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Ventricular fibrillation			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	2 / 119 (1.68%)
occurrences (all)	0	0	2
Supraventricular extrasystoles			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Sinus bradycardia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Pericardial effusion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Myocarditis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Myocardial ischaemia			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	35 / 1736 (2.02%)	63 / 3461 (1.82%)	5 / 119 (4.20%)
occurrences (all)	37	67	6

Amnesia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Anosmia			
subjects affected / exposed	30 / 1736 (1.73%)	57 / 3461 (1.65%)	5 / 119 (4.20%)
occurrences (all)	31	60	7
Aphasia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Balance disorder			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Clonus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Bell's palsy			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Burning sensation			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Carotid artery occlusion			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Cerebrovascular accident			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Cervical radiculopathy			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	0	4	1
Dysgeusia			
subjects affected / exposed	6 / 1736 (0.35%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	6	4	0
Dysarthria			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0



Dizziness			
subjects affected / exposed	22 / 1736 (1.27%)	52 / 3461 (1.50%)	3 / 119 (2.52%)
occurrences (all)	28	56	5
Depressed level of consciousness			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Dementia			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Encephalopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hyposmia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Hypoaesthesia			
subjects affected / exposed	4 / 1736 (0.23%)	13 / 3461 (0.38%)	1 / 119 (0.84%)
occurrences (all)	4	13	1
Headache			
subjects affected / exposed	211 / 1736 (12.15%)	439 / 3461 (12.68%)	33 / 119 (27.73%)
occurrences (all)	252	564	42
Head discomfort			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Essential tremor			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Intercostal neuralgia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Intraneural cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lethargy			

subjects affected / exposed	5 / 1736 (0.29%)	7 / 3461 (0.20%)	1 / 119 (0.84%)
occurrences (all)	5	7	1
Loss of consciousness			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Memory impairment			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Migraine			
subjects affected / exposed	8 / 1736 (0.46%)	24 / 3461 (0.69%)	2 / 119 (1.68%)
occurrences (all)	10	27	2
Movement disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Myoclonus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nerve compression			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	3	3	0
Neuralgia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Neuropathy peripheral			
subjects affected / exposed	7 / 1736 (0.40%)	3 / 3461 (0.09%)	2 / 119 (1.68%)
occurrences (all)	7	3	2
Ophthalmic migraine			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	10 / 1736 (0.58%)	17 / 3461 (0.49%)	2 / 119 (1.68%)
occurrences (all)	10	17	2
Presyncope			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Post-traumatic headache			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Parosmia			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Psychomotor hyperactivity			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	2	1	1
Sciatica			
subjects affected / exposed	7 / 1736 (0.40%)	16 / 3461 (0.46%)	2 / 119 (1.68%)
occurrences (all)	8	17	2
Seizure			
subjects affected / exposed	3 / 1736 (0.17%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	5	6	0
Sinus headache			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Somnolence			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Syncope			
subjects affected / exposed	3 / 1736 (0.17%)	16 / 3461 (0.46%)	1 / 119 (0.84%)
occurrences (all)	3	17	1
Tension headache			
subjects affected / exposed	3 / 1736 (0.17%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	3	0	0
Tremor			
subjects affected / exposed	2 / 1736 (0.12%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences (all)	2	6	0
Transient ischaemic attack			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Altered state of consciousness			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Carpal tunnel syndrome			
subjects affected / exposed	3 / 1736 (0.17%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	3	1	0
Carotid artery thrombosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Cerebral infarction			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Cerebral congestion			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Cerebral atrophy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Cerebral artery occlusion			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cerebellar infarction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Central pain syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ataxia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Axonal neuropathy			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Carotid arteriosclerosis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Carotid artery stenosis			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	1	4	1
Cubital tunnel syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Cranial nerve disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Complex regional pain syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Cognitive disorder			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	5	0
Cluster headache			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Diabetic neuropathy			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Cervicogenic headache			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Cerebral microangiopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cerebral ischaemia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hypersomnia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hemiparesis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Fine motor skill dysfunction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Facial paresis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Dizziness postural			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hypogeusia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Migraine with aura			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Metabolic encephalopathy			

subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Mental impairment			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Leukoencephalopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lacunar infarction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Radiculopathy			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Radicular pain			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Polyneuropathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Piriformis syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Peripheral nerve lesion			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Parkinson's disease			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Osmotic demyelination syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Normal pressure hydrocephalus			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Myelopathy			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Peroneal nerve palsy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Vascular dementia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Trigeminal neuralgia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Transient global amnesia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Spinal claudication			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	17 / 1736 (0.98%)	37 / 3461 (1.07%)	3 / 119 (2.52%)
occurrences (all)	17	37	3



Increased tendency to bruise subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	3 / 3461 (0.09%) 3	2 / 119 (1.68%) 3
Leukopenia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	5 / 3461 (0.14%) 5	0 / 119 (0.00%) 0
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Neutrophilia subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	5 / 3461 (0.14%) 6	0 / 119 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	8 / 1736 (0.46%) 8	15 / 3461 (0.43%) 18	2 / 119 (1.68%) 2
Normochromic normocytic anaemia subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Normocytic anaemia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Polycythaemia subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Splenomegaly subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0

Thrombocytopenia			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	3	3	0
Febrile neutropenia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Deficiency anaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Coagulopathy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Blood loss anaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Anaemia of chronic disease			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Bone marrow oedema			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hilar lymphadenopathy			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Hyperleukocytosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypochromic anaemia			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lymph node pain			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Macrocytosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Microcytic anaemia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Pancytopenia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Deafness unilateral			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Cerumen impaction			
subjects affected / exposed	1 / 1736 (0.06%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences (all)	1	9	1
Vertigo			
subjects affected / exposed	7 / 1736 (0.40%)	17 / 3461 (0.49%)	0 / 119 (0.00%)
occurrences (all)	9	20	0

Tinnitus			
subjects affected / exposed	3 / 1736 (0.17%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	3	7	0
Inner ear inflammation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Ear pain			
subjects affected / exposed	9 / 1736 (0.52%)	13 / 3461 (0.38%)	1 / 119 (0.84%)
occurrences (all)	9	13	2
Sudden hearing loss			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Presbycusis			
subjects affected / exposed	3 / 1736 (0.17%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	3	1	0
Otorrhoea			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Middle ear effusion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Haematotympanum			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
External ear inflammation			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Eustachian tube dysfunction			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

Ear congestion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ear canal erythema			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Deafness bilateral			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Superior semicircular canal dehiscence			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Deafness			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	1	1
Tympanic membrane perforation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vertigo positional			
subjects affected / exposed	0 / 1736 (0.00%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Cataract			
subjects affected / exposed	5 / 1736 (0.29%)	11 / 3461 (0.32%)	1 / 119 (0.84%)
occurrences (all)	5	12	1
Conjunctivitis allergic			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Dry age-related macular degeneration			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	4 / 1736 (0.23%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	4	9	0
Eye allergy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Eye pain			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	2	4	1
Eye pruritus			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	1	4	1
Eye swelling			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Lacrimation increased			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	1	6	0
Ocular hyperaemia			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Periorbital oedema			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Periorbital swelling			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Periorbital pain			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Scleritis			

subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Vision blurred			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Vitreous floaters			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Age-related macular degeneration			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Asthenopia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Astigmatism			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Chalazion			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Dermatochalasis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Diabetic retinopathy			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Erythema of eyelid			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Eye inflammation			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Glaucoma			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Keratitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Macular degeneration			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	2 / 119 (1.68%)
occurrences (all)	0	1	2
Macular fibrosis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Macular oedema			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Ocular hypertension			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Ophthalmoplegia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Diabetic retinal oedema			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Vitreous detachment			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Vitreous adhesions			



subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Visual field defect			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Uveitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Orbital oedema			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Retinal detachment			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Pterygium			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Presbyopia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Posterior capsule opacification			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Photophobia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Retinal tear			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0

Abdominal distension subjects affected / exposed occurrences (all)	7 / 1736 (0.40%) 8	9 / 3461 (0.26%) 9	0 / 119 (0.00%) 0
Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	19 / 1736 (1.09%) 21	29 / 3461 (0.84%) 30	4 / 119 (3.36%) 5
Abdominal rigidity subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	7 / 1736 (0.40%) 7	21 / 3461 (0.61%) 22	1 / 119 (0.84%) 1
Abdominal pain lower subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	11 / 3461 (0.32%) 11	0 / 119 (0.00%) 0
Abdominal tenderness subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Anal polyp subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Aphthous ulcer subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Change of bowel habit subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Dental caries subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	5 / 3461 (0.14%) 6	0 / 119 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	11 / 1736 (0.63%) 12	25 / 3461 (0.72%) 26	3 / 119 (2.52%) 3

Colitis			
subjects affected / exposed	4 / 1736 (0.23%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	4	4	0
Diarrhoea			
subjects affected / exposed	81 / 1736 (4.67%)	183 / 3461 (5.29%)	16 / 119 (13.45%)
occurrences (all)	91	206	22
Dry mouth			
subjects affected / exposed	5 / 1736 (0.29%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	5	7	0
Diverticulum intestinal			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Diverticulum			
subjects affected / exposed	0 / 1736 (0.00%)	11 / 3461 (0.32%)	3 / 119 (2.52%)
occurrences (all)	0	11	3
Dyspepsia			
subjects affected / exposed	7 / 1736 (0.40%)	13 / 3461 (0.38%)	0 / 119 (0.00%)
occurrences (all)	7	13	0
Dysphagia			
subjects affected / exposed	1 / 1736 (0.06%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	1	7	0
Faeces discoloured			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	4 / 1736 (0.23%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	4	4	0
Flatulence			
subjects affected / exposed	4 / 1736 (0.23%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	4	0	0
Faeces soft			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Frequent bowel movements			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Gingival pain			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Gingival disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	14 / 1736 (0.81%)	28 / 3461 (0.81%)	5 / 119 (4.20%)
occurrences (all)	15	28	5
Gastritis			
subjects affected / exposed	3 / 1736 (0.17%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	3	10	0
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Impaired gastric emptying			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Hypoaesthesia oral			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	1	1
Hyperaesthesia teeth			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hiatus hernia			
subjects affected / exposed	1 / 1736 (0.06%)	9 / 3461 (0.26%)	1 / 119 (0.84%)
occurrences (all)	1	9	1
Haemorrhoids			
subjects affected / exposed	4 / 1736 (0.23%)	15 / 3461 (0.43%)	0 / 119 (0.00%)
occurrences (all)	4	15	0
Irritable bowel syndrome			
subjects affected / exposed	2 / 1736 (0.12%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	2	8	0

Haematochezia			
subjects affected / exposed	3 / 1736 (0.17%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	4	4	1
Large intestine polyp			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Oral mucosal blistering			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oral disorder			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	75 / 1736 (4.32%)	163 / 3461 (4.71%)	8 / 119 (6.72%)
occurrences (all)	82	191	12
Mouth ulceration			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	1 / 119 (0.84%)
occurrences (all)	1	5	1
Mouth haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lip disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Salivary gland enlargement			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Peptic ulcer			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Paraesthesia oral			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Pancreatitis			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0

Oral pain			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oral mucosal eruption			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Swollen tongue			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Tongue ulceration			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Tongue disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Tongue discomfort			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Tooth impacted			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Vomiting			
subjects affected / exposed	30 / 1736 (1.73%)	60 / 3461 (1.73%)	3 / 119 (2.52%)
occurrences (all)	33	75	3
Toothache			
subjects affected / exposed	2 / 1736 (0.12%)	17 / 3461 (0.49%)	0 / 119 (0.00%)
occurrences (all)	2	18	0
Anal fissure			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Abdominal mass			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Anal fistula			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0

Anal pruritus			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Anal skin tags			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Angular cheilitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Anogenital dysplasia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	3	0	0
Apical granuloma			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Bile acid malabsorption			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Bowel movement irregularity			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Anorectal disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0

Crohn's disease			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Diaphragmatic hernia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Duodenal ulcer			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Duodenitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Dyskinesia oesophageal			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Colitis microscopic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Eructation			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Gastric ulcer			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	1	3	1
Coeliac disease			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0



Gastritis alcoholic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastritis erosive			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal motility disorder			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal mucosa hyperaemia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Giant cell epulis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Glossitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Haematemesis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Haemorrhoids thrombosed			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0

Ileus			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Inflammatory bowel disease			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	3 / 1736 (0.17%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	3	1	1
Inguinal hernia strangulated			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Large intestinal stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Large intestinal ulcer			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Oesophageal motility disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Melaena			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Odynophagia			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Oesophageal dilatation			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Oesophageal disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Loose tooth			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oesophageal spasm			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oesophageal stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Oesophagitis			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Pancreatic failure			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	2	0	1
Pancreatic mass			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Pancreatic steatosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Salivary gland disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Periodontal disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Plicated tongue			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	2	5	0

Rectal polyp			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Pancreatitis chronic			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Salivary gland mucocoele			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Sigmoid mesocolon hernia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Submaxillary gland enlargement			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tongue geographic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tooth disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tooth loss			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Trichoglossia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Umbilical hernia subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	5 / 3461 (0.14%) 5	0 / 119 (0.00%) 0
Tongue erythema subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Uvulitis subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	7 / 3461 (0.20%) 7	0 / 119 (0.00%) 0
Dermal cyst subjects affected / exposed occurrences (all)	4 / 1736 (0.23%) 5	5 / 3461 (0.14%) 5	0 / 119 (0.00%) 0
Dermatitis subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Dermatitis allergic subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Dermatitis atopic subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Dermatitis contact subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	10 / 3461 (0.29%) 10	0 / 119 (0.00%) 0
Diabetic wound subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 2	0 / 119 (0.00%) 0
Actinic keratosis			

subjects affected / exposed	3 / 1736 (0.17%)	7 / 3461 (0.20%)	4 / 119 (3.36%)
occurrences (all)	3	7	5
Angioedema			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Ecchymosis			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Eczema			
subjects affected / exposed	3 / 1736 (0.17%)	7 / 3461 (0.20%)	1 / 119 (0.84%)
occurrences (all)	5	7	1
Erythema			
subjects affected / exposed	3 / 1736 (0.17%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	3	7	0
Dry skin			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Hyperhidrosis			
subjects affected / exposed	5 / 1736 (0.29%)	7 / 3461 (0.20%)	1 / 119 (0.84%)
occurrences (all)	5	7	1
Ingrowing nail			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Intertrigo			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Lichen sclerosus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	1 / 1736 (0.06%)	11 / 3461 (0.32%)	1 / 119 (0.84%)
occurrences (all)	1	12	1
Miliaria			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Macule			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	13 / 1736 (0.75%)	21 / 3461 (0.61%)	1 / 119 (0.84%)
occurrences (all)	13	21	1
Pityriasis rosea			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Psoriasis			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	2	5	0
Rash			
subjects affected / exposed	22 / 1736 (1.27%)	41 / 3461 (1.18%)	3 / 119 (2.52%)
occurrences (all)	22	46	4
Rash erythematous			
subjects affected / exposed	3 / 1736 (0.17%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	3	1	0
Rash papular			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Rash pruritic			
subjects affected / exposed	3 / 1736 (0.17%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	3	4	0
Skin lesion			

subjects affected / exposed	8 / 1736 (0.46%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	9	5	1
Urticaria			
subjects affected / exposed	5 / 1736 (0.29%)	11 / 3461 (0.32%)	0 / 119 (0.00%)
occurrences (all)	6	12	0
Skin ulcer			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	1	3	1
Skin striae			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Blister			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	2	1	1
Cold sweat			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Decubitus ulcer			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Drug eruption			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Granuloma annulare			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hand dermatitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hidradenitis			



subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Photosensitivity reaction			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	1	4	1
Hyperkeratosis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Hyperkeratosis follicularis et parafollicularis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lipodystrophy acquired			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Penile ulceration			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Photodermatosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hirsutism			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pigmentation disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pruritus allergic			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Purpura			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Purpura senile			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Rash macular subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Sensitive skin subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Skin oedema subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Skin plaque subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Rosacea subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	3 / 3461 (0.09%) 3	0 / 119 (0.00%) 0
Renal and urinary disorders			
Crystalluria subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Chronic kidney disease subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	7 / 3461 (0.20%) 7	0 / 119 (0.00%) 0
Chromaturia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Calculus bladder subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	1 / 3461 (0.03%) 1	1 / 119 (0.84%) 1
Bladder spasm subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
Bladder cyst			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Acute kidney injury			
subjects affected / exposed	10 / 1736 (0.58%)	5 / 3461 (0.14%)	2 / 119 (1.68%)
occurrences (all)	11	5	2
Micturition disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Hypertonic bladder			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	0	4	1
Hydronephrosis			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	10 / 1736 (0.58%)	22 / 3461 (0.64%)	0 / 119 (0.00%)
occurrences (all)	10	23	0
Dysuria			
subjects affected / exposed	2 / 1736 (0.12%)	9 / 3461 (0.26%)	1 / 119 (0.84%)
occurrences (all)	2	9	1
Nephrolithiasis			
subjects affected / exposed	8 / 1736 (0.46%)	13 / 3461 (0.38%)	2 / 119 (1.68%)
occurrences (all)	9	13	2
Nocturia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Pollakiuria			
subjects affected / exposed	3 / 1736 (0.17%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	3	4	1
Proteinuria			

subjects affected / exposed	2 / 1736 (0.12%)	6 / 3461 (0.17%)	0 / 119 (0.00%)
occurrences (all)	2	7	0
Renal colic			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Renal cyst			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	1	3	1
Renal failure			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Renal impairment			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Stress urinary incontinence			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Ureterolithiasis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Urethral meatus stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Urge incontinence			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Urinary retention			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Urinary incontinence			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	1	4	1
End stage renal disease			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Glycosuria			

subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Lupus nephritis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Microalbuminuria			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Stag horn calculus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Bladder outlet obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Urethral stenosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Hyperthyroidism			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Hypogonadism			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Hypothyroidism			
subjects affected / exposed	5 / 1736 (0.29%)	9 / 3461 (0.26%)	1 / 119 (0.84%)
occurrences (all)	5	9	1

Goitre			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	2 / 119 (1.68%)
occurrences (all)	0	2	2
Addison's disease			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Adrenomegaly			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Thyroid mass			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	2	0	1
Hyperparathyroidism			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Hypothalamo-pituitary disorder			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pituitary cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Primary hypogonadism			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Thyroid atrophy			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Androgen deficiency			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Ankle deformity			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Arthralgia			

subjects affected / exposed	51 / 1736 (2.94%)	122 / 3461 (3.52%)	5 / 119 (4.20%)
occurrences (all)	56	137	5
Bursitis			
subjects affected / exposed	7 / 1736 (0.40%)	7 / 3461 (0.20%)	2 / 119 (1.68%)
occurrences (all)	7	8	2
Back pain			
subjects affected / exposed	53 / 1736 (3.05%)	85 / 3461 (2.46%)	2 / 119 (1.68%)
occurrences (all)	57	90	3
Arthritis			
subjects affected / exposed	7 / 1736 (0.40%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	7	9	0
Dupuytren's contracture			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Coccydynia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	3	0	0
Cervical spinal stenosis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Femoroacetabular impingement			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Fibromyalgia			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Flank pain			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	2	6	0
Foot deformity			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Joint hyperextension			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Intervertebral disc protrusion			
subjects affected / exposed	9 / 1736 (0.52%)	11 / 3461 (0.32%)	1 / 119 (0.84%)
occurrences (all)	10	11	1
Intervertebral disc degeneration			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	2	4	1
Groin pain			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Joint swelling			
subjects affected / exposed	2 / 1736 (0.12%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	2	7	0
Muscular weakness			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	1	4	1
Muscle tightness			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Muscle spasms			
subjects affected / exposed	7 / 1736 (0.40%)	22 / 3461 (0.64%)	1 / 119 (0.84%)
occurrences (all)	7	22	1
Limb discomfort			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal chest pain			
subjects affected / exposed	6 / 1736 (0.35%)	17 / 3461 (0.49%)	0 / 119 (0.00%)
occurrences (all)	6	17	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Myalgia			



subjects affected / exposed	90 / 1736 (5.18%)	185 / 3461 (5.35%)	20 / 119 (16.81%)
occurrences (all)	102	207	25
Neck pain			
subjects affected / exposed	12 / 1736 (0.69%)	12 / 3461 (0.35%)	2 / 119 (1.68%)
occurrences (all)	12	12	2
Osteoarthritis			
subjects affected / exposed	20 / 1736 (1.15%)	35 / 3461 (1.01%)	3 / 119 (2.52%)
occurrences (all)	21	37	4
Musculoskeletal stiffness			
subjects affected / exposed	4 / 1736 (0.23%)	11 / 3461 (0.32%)	0 / 119 (0.00%)
occurrences (all)	4	14	0
Osteopenia			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	0	3	1
Osteoporosis			
subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	4	8	0
Osteoporotic fracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	25 / 1736 (1.44%)	45 / 3461 (1.30%)	0 / 119 (0.00%)
occurrences (all)	27	49	0
Psoriatic arthropathy			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	1	5	0
Periarthritis			
subjects affected / exposed	5 / 1736 (0.29%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	5	2	1
Plantar fasciitis			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	2 / 119 (1.68%)
occurrences (all)	1	5	2
Polyarthritis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Rhabdomyolysis			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Rheumatoid arthritis			
subjects affected / exposed	1 / 1736 (0.06%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	1	10	0
Rotator cuff syndrome			
subjects affected / exposed	9 / 1736 (0.52%)	3 / 3461 (0.09%)	2 / 119 (1.68%)
occurrences (all)	9	3	2
Sacroiliitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Tendon disorder			
subjects affected / exposed	4 / 1736 (0.23%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	4	4	1
Spinal pain			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Synovial cyst			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	0	5	0
Spinal osteoarthritis			
subjects affected / exposed	2 / 1736 (0.12%)	10 / 3461 (0.29%)	0 / 119 (0.00%)
occurrences (all)	2	11	0
Tendon pain			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	3 / 1736 (0.17%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences (all)	3	7	1
Trigger finger			

subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	3	2	1
Bone pain			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Ankylosing spondylitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Arthropathy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Chondrocalcinosis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Chondromalacia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Costochondritis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Diastasis recti abdominis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Enostosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Enthesopathy			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc displacement			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Exostosis of jaw			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Facet joint syndrome			

subjects affected / exposed	3 / 1736 (0.17%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	3	2	0
Haemarthrosis			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Intervertebral disc compression			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Intervertebral disc disorder			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Exostosis			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Joint ankylosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Joint contracture			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Joint effusion			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Joint noise			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Myositis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Limb mass			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Lumbar spinal stenosis			

subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Mobility decreased			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Morphoea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Muscle atrophy			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Joint stiffness			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Pathological fracture			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Pelvic deformity			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Scapholunate dissociation			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Scoliosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Sjogren's syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Spinal stenosis			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Spondylitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Spondylolisthesis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Synovitis			
subjects affected / exposed	0 / 1736 (0.00%)	4 / 3461 (0.12%)	1 / 119 (0.84%)
occurrences (all)	0	4	1
Tendon calcification			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Osteolysis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Soft tissue mass			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	2
Tenosynovitis stenosans			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Trismus			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vertebral foraminal stenosis			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	2	0	1
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 1736 (0.06%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	1	9	0

Anal chlamydia infection			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Bronchitis			
subjects affected / exposed	10 / 1736 (0.58%)	32 / 3461 (0.92%)	2 / 119 (1.68%)
occurrences (all)	10	35	3
Asymptomatic bacteriuria			
subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Bacteraemia			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Bacterial vaginosis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	2
Arthritis bacterial			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	6 / 1736 (0.35%)	14 / 3461 (0.40%)	1 / 119 (0.84%)
occurrences (all)	6	14	1
Chlamydial infection			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	0	3	2
Chronic sinusitis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Conjunctivitis			
subjects affected / exposed	4 / 1736 (0.23%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	4	4	0
Diverticulitis			
subjects affected / exposed	1 / 1736 (0.06%)	9 / 3461 (0.26%)	2 / 119 (1.68%)
occurrences (all)	1	11	2
Cystitis			
subjects affected / exposed	7 / 1736 (0.40%)	19 / 3461 (0.55%)	1 / 119 (0.84%)
occurrences (all)	7	22	4

Cystitis escherichia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Dermatophytosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Diarrhoea infectious			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Ear infection			
subjects affected / exposed	9 / 1736 (0.52%)	14 / 3461 (0.40%)	0 / 119 (0.00%)
occurrences (all)	10	14	0
Epididymitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Escherichia infection			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Eye abscess			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Fungal skin infection			
subjects affected / exposed	7 / 1736 (0.40%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences (all)	7	6	1
Febrile infection			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Folliculitis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Fungal infection			
subjects affected / exposed	3 / 1736 (0.17%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	3	4	0



Eye infection			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	1	5	0
Furuncle			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis			
subjects affected / exposed	10 / 1736 (0.58%)	21 / 3461 (0.61%)	1 / 119 (0.84%)
occurrences (all)	10	21	1
Gingival abscess			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Impetigo			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	1	2	1
Herpes zoster			
subjects affected / exposed	7 / 1736 (0.40%)	16 / 3461 (0.46%)	2 / 119 (1.68%)
occurrences (all)	7	16	2
Hordeolum			
subjects affected / exposed	1 / 1736 (0.06%)	8 / 3461 (0.23%)	1 / 119 (0.84%)
occurrences (all)	1	9	1
Gonorrhoea			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Infected dermal cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Infected skin ulcer			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0

Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	5 / 1736 (0.29%)	12 / 3461 (0.35%)	0 / 119 (0.00%)
occurrences (all)	6	13	0
Laryngitis			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	3	0
Localised infection			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	1 / 119 (0.84%)
occurrences (all)	1	6	1
Lower respiratory tract infection			
subjects affected / exposed	20 / 1736 (1.15%)	27 / 3461 (0.78%)	2 / 119 (1.68%)
occurrences (all)	22	30	2
Nail bed infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	26 / 1736 (1.50%)	42 / 3461 (1.21%)	4 / 119 (3.36%)
occurrences (all)	26	47	5
Onychomycosis			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Paronychia			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Otitis media			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Periodontitis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Pelvic inflammatory disease			

subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	2
Otitis externa			
subjects affected / exposed	4 / 1736 (0.23%)	8 / 3461 (0.23%)	1 / 119 (0.84%)
occurrences (all)	5	9	1
Oral infection			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Oral herpes			
subjects affected / exposed	8 / 1736 (0.46%)	14 / 3461 (0.40%)	1 / 119 (0.84%)
occurrences (all)	9	14	1
Oral fungal infection			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Post procedural pneumonia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Peritonsillar abscess			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Pyelonephritis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Pustule			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	12 / 1736 (0.69%)	17 / 3461 (0.49%)	3 / 119 (2.52%)
occurrences (all)	13	18	4
Pharyngitis bacterial			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Pharyngitis streptococcal			

subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	4	0
Pilonidal cyst			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	4 / 1736 (0.23%)	21 / 3461 (0.61%)	1 / 119 (0.84%)
occurrences (all)	4	22	1
Sinusitis bacterial			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Skin bacterial infection			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Skin infection			
subjects affected / exposed	2 / 1736 (0.12%)	7 / 3461 (0.20%)	0 / 119 (0.00%)
occurrences (all)	2	7	0
Staphylococcal infection			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Pyuria			
subjects affected / exposed	5 / 1736 (0.29%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	5	10	0
Secondary syphilis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Rhinitis			
subjects affected / exposed	15 / 1736 (0.86%)	34 / 3461 (0.98%)	3 / 119 (2.52%)
occurrences (all)	18	37	3
Respiratory tract infection viral			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	6 / 1736 (0.35%)	5 / 3461 (0.14%)	2 / 119 (1.68%)
occurrences (all)	6	5	2
Sinusitis			

subjects affected / exposed	19 / 1736 (1.09%)	34 / 3461 (0.98%)	3 / 119 (2.52%)
occurrences (all)	23	39	3
Staphylococcal skin infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Upper respiratory tract infection			
subjects affected / exposed	34 / 1736 (1.96%)	54 / 3461 (1.56%)	8 / 119 (6.72%)
occurrences (all)	44	59	8
Tooth infection			
subjects affected / exposed	6 / 1736 (0.35%)	15 / 3461 (0.43%)	1 / 119 (0.84%)
occurrences (all)	6	15	1
Tooth abscess			
subjects affected / exposed	5 / 1736 (0.29%)	14 / 3461 (0.40%)	1 / 119 (0.84%)
occurrences (all)	5	14	1
Tonsillitis			
subjects affected / exposed	3 / 1736 (0.17%)	8 / 3461 (0.23%)	0 / 119 (0.00%)
occurrences (all)	3	8	0
Tinea versicolour			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	1	1
Tinea pedis			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	1 / 119 (0.84%)
occurrences (all)	1	3	1
Syphilis			
subjects affected / exposed	5 / 1736 (0.29%)	6 / 3461 (0.17%)	1 / 119 (0.84%)
occurrences (all)	5	6	1
Urinary tract infection			
subjects affected / exposed	59 / 1736 (3.40%)	122 / 3461 (3.52%)	10 / 119 (8.40%)
occurrences (all)	63	146	16
Vaginal cellulitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Wound infection			

subjects affected / exposed	2 / 1736 (0.12%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	2	2	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Viral upper respiratory tract infection			
subjects affected / exposed	7 / 1736 (0.40%)	15 / 3461 (0.43%)	0 / 119 (0.00%)
occurrences (all)	7	15	0
Viral rhinitis			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Viral infection			
subjects affected / exposed	12 / 1736 (0.69%)	21 / 3461 (0.61%)	3 / 119 (2.52%)
occurrences (all)	12	23	3
Viraemia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Abdominal abscess			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Abscess limb			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Acarodermatitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Anal candidiasis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Balanitis candida			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Arteriovenous graft site infection			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Atypical pneumonia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Bacterial disease carrier			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Bacterial infection			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Bacteriuria			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Appendicitis			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Bronchitis bacterial			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Candida infection			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Enterobiasis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1

Coccidioidomycosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Cytomegalovirus infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Dacryocanaliculitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Dengue haemorrhagic fever			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Device related infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Cervicitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	1
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Fungaemia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 1736 (0.06%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	1	5	0
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0



Helicobacter infection			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	1	1	1
Genital herpes			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Genitourinary chlamydia infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Gonococcal infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	1	0	2
Groin infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Haemophilus infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Infected bite			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Infected cyst			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	4	0
Infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0

Infectious pleural effusion			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	3 / 1736 (0.17%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	3	4	0
Intervertebral discitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Klebsiella infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Labyrinthitis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Lung abscess			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lyme disease			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Lymphangitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Mastitis			

subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Mastoiditis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Medical device site abscess			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal gonococcal infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	1 / 119 (0.84%)
occurrences (all)	0	0	1
Mucormycosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Nasal vestibulitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Norovirus infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Orchitis			
subjects affected / exposed	1 / 1736 (0.06%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Molluscum contagiosum			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Osteomyelitis			
subjects affected / exposed	2 / 1736 (0.12%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	2	0	0
Otitis media acute			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Papilloma viral infection			

subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Perichondritis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pertussis			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Pneumonia bacterial			
subjects affected / exposed	3 / 1736 (0.17%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	3	1	1
Pneumonia klebsiella			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Pneumonia viral			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Post procedural infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Postoperative wound infection			
subjects affected / exposed	3 / 1736 (0.17%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	3	3	0
Proctitis gonococcal			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	2 / 119 (1.68%)
occurrences (all)	0	0	2
Respiratory tract chlamydial infection			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Root canal infection			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Sialoadenitis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Sinusitis fungal			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	1 / 119 (0.84%)
occurrences (all)	0	2	1
Staphylococcal abscess			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Systemic candida			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Tinea infection			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Trichomoniasis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Spirochaetal infection			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0

Urethritis gonococcal subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Urinary tract infection staphylococcal subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
Viral diarrhoea subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 1736 (0.00%) 0	1 / 3461 (0.03%) 1	0 / 119 (0.00%) 0
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	3 / 3461 (0.09%) 3	1 / 119 (0.84%) 1
Asymptomatic COVID-19 subjects affected / exposed occurrences (all)	17 / 1736 (0.98%) 17	28 / 3461 (0.81%) 28	7 / 119 (5.88%) 7
Post-acute COVID-19 syndrome subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 4	1 / 3461 (0.03%) 1	2 / 119 (1.68%) 2
Hepatitis C subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
HIV peripheral neuropathy subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	0 / 119 (0.00%) 0
COVID-19 pneumonia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	0 / 3461 (0.00%) 0	1 / 119 (0.84%) 1
COVID-19 subjects affected / exposed occurrences (all)	229 / 1736 (13.19%) 240	465 / 3461 (13.44%) 475	35 / 119 (29.41%) 39

Suspected COVID-19 subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	4 / 3461 (0.12%) 5	0 / 119 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	30 / 1736 (1.73%) 35	67 / 3461 (1.94%) 75	9 / 119 (7.56%) 10
Hyperglycaemia subjects affected / exposed occurrences (all)	9 / 1736 (0.52%) 9	24 / 3461 (0.69%) 24	1 / 119 (0.84%) 1
Hyperkalaemia subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 2	6 / 3461 (0.17%) 6	0 / 119 (0.00%) 0
Diabetes mellitus subjects affected / exposed occurrences (all)	10 / 1736 (0.58%) 11	11 / 3461 (0.32%) 11	1 / 119 (0.84%) 1
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	4 / 3461 (0.12%) 4	1 / 119 (0.84%) 1
Hypercholesterolaemia subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	18 / 3461 (0.52%) 18	5 / 119 (4.20%) 6
Glucose tolerance impaired subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	8 / 3461 (0.23%) 8	1 / 119 (0.84%) 1
Gout subjects affected / exposed occurrences (all)	2 / 1736 (0.12%) 4	13 / 3461 (0.38%) 13	0 / 119 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 1736 (0.06%) 1	2 / 3461 (0.06%) 2	0 / 119 (0.00%) 0
Folate deficiency subjects affected / exposed occurrences (all)	3 / 1736 (0.17%) 3	8 / 3461 (0.23%) 8	0 / 119 (0.00%) 0
Hyperlipidaemia			

subjects affected / exposed	9 / 1736 (0.52%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	9	9	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Hypocalcaemia			
subjects affected / exposed	2 / 1736 (0.12%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	2	1	0
Hypoglycaemia			
subjects affected / exposed	2 / 1736 (0.12%)	4 / 3461 (0.12%)	0 / 119 (0.00%)
occurrences (all)	2	5	0
Iron deficiency			
subjects affected / exposed	2 / 1736 (0.12%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	2	3	0
Hyponatraemia			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Hypovitaminosis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Increased appetite			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Hypokalaemia			
subjects affected / exposed	3 / 1736 (0.17%)	9 / 3461 (0.26%)	0 / 119 (0.00%)
occurrences (all)	3	11	0
Obesity			
subjects affected / exposed	0 / 1736 (0.00%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	0	3	0
Type 2 diabetes mellitus			
subjects affected / exposed	8 / 1736 (0.46%)	18 / 3461 (0.52%)	3 / 119 (2.52%)
occurrences (all)	8	18	3
Calciophylaxis			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Dehydration			



subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	3 / 119 (2.52%)
occurrences (all)	0	1	3
Dyslipidaemia			
subjects affected / exposed	0 / 1736 (0.00%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	0	2	0
Fluid overload			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0
Histamine intolerance			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Malnutrition			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	1 / 119 (0.84%)
occurrences (all)	0	1	1
Hypomagnesaemia			
subjects affected / exposed	1 / 1736 (0.06%)	3 / 3461 (0.09%)	0 / 119 (0.00%)
occurrences (all)	1	4	0
Hypophagia			
subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 1736 (0.06%)	2 / 3461 (0.06%)	0 / 119 (0.00%)
occurrences (all)	1	2	0
Hypovolaemia			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Lactic acidosis			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 1736 (0.00%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			

subjects affected / exposed	1 / 1736 (0.06%)	0 / 3461 (0.00%)	0 / 119 (0.00%)
occurrences (all)	1	0	0
Metabolic syndrome			
subjects affected / exposed	0 / 1736 (0.00%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency			
subjects affected / exposed	10 / 1736 (0.58%)	23 / 3461 (0.66%)	3 / 119 (2.52%)
occurrences (all)	10	24	3
Vitamin B12 deficiency			
subjects affected / exposed	2 / 1736 (0.12%)	5 / 3461 (0.14%)	0 / 119 (0.00%)
occurrences (all)	2	5	0
Vitamin B complex deficiency			
subjects affected / exposed	1 / 1736 (0.06%)	1 / 3461 (0.03%)	0 / 119 (0.00%)
occurrences (all)	1	1	0

<b>Non-serious adverse events</b>	Group 1	Group 3b	Group 3a
Total subjects affected by non-serious adverse events			
subjects affected / exposed	185 / 234 (79.06%)	55 / 74 (74.32%)	58 / 76 (76.32%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Basal cell carcinoma			
subjects affected / exposed	5 / 234 (2.14%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	6	0	0
Malignant melanoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Benign neoplasm of skin			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	2	0
Blepharal papilloma			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Eyelid tumour			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lipoma			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Benign breast neoplasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Prostate cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic keratosis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Skin papilloma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal wall neoplasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Benign hepatic neoplasm			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Benign salivary gland neoplasm			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bowen's disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cancer fatigue			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Colon adenoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Colon cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Essential thrombocythaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fibroma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haemangioma			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Haemangioma of bone			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hair follicle tumour benign			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dysplastic naevus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Neoplasm malignant			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neoplasm skin			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Leiomyoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lung carcinoma cell type unspecified recurrent			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lung neoplasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Nasal cavity cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Meningioma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Metastases to liver			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Metastases to lymph nodes			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Naevus haemorrhage			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Malignant neoplasm of eyelid			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Papilloma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Parathyroid tumour benign			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Plasma cell myeloma recurrent			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Salivary gland cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Skin cancer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Thyroid cancer			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tongue neoplasm benign			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tumour pain			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Spinal cord neoplasm			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Arteriovenous fistula			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Essential hypertension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Aortic dilatation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	12 / 234 (5.13%)	6 / 74 (8.11%)	8 / 76 (10.53%)
occurrences (all)	12	6	9
Hypotension			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0

Venous thrombosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Varicose vein			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis limb			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
White coat hypertension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Angiodysplasia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aortic aneurysm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aortic arteriosclerosis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Aortic stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0



Blood pressure fluctuation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood pressure inadequately controlled			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Circulatory collapse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertensive emergency			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertensive urgency			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intermittent claudication			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Neurogenic shock			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertensive crisis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Raynaud's phenomenon			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Shock haemorrhagic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vascular pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Haemorrhage in pregnancy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	2	1	1
Axillary pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	54 / 234 (23.08%)	6 / 74 (8.11%)	11 / 76 (14.47%)
occurrences (all)	68	6	14
Chills			
subjects affected / exposed	21 / 234 (8.97%)	5 / 74 (6.76%)	6 / 76 (7.89%)
occurrences (all)	22	5	7
Chronic fatigue syndrome			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Facial discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Feeling cold			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Feeling jittery			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	3	0	1
Injection site bruising			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site joint pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	4 / 76 (5.26%)
occurrences (all)	1	0	5
Injection site paraesthesia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	8 / 234 (3.42%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	8	0	1
Injection site reaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site urticaria			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injury associated with device			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Medical device site irritation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0
Pain			
subjects affected / exposed	25 / 234 (10.68%)	5 / 74 (6.76%)	8 / 76 (10.53%)
occurrences (all)	30	5	9
Vaccination site erythema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	23 / 234 (9.83%)	5 / 74 (6.76%)	6 / 76 (7.89%)
occurrences (all)	28	5	7
Sensation of foreign body			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Swelling face			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaccination site discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	2	1	0
Vessel puncture site haematoma			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaccination site mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaccination site reaction			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Feeling abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Catheter site swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Crepitations			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Cyst			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Foaming at mouth			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Generalised oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Puncture site pruritus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Retention cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Secretion discharge			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Systemic inflammatory response syndrome			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Puncture site oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anaphylactic reaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Allergy to chemicals			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed	4 / 234 (1.71%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	5	1	0
Allergy to arthropod sting			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Allergy to plants			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Food allergy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Primary amyloidosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sarcoidosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mite allergy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Social circumstances			
Physical abuse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Physical assault			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Alcohol use			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Menopause			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abnormal uterine bleeding			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 234 (0.43%)	2 / 74 (2.70%)	1 / 76 (1.32%)
occurrences (all)	1	2	1
Breast mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Breast swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ejaculation failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Menometrorrhagia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Menopausal disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Menopausal symptoms			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pelvic adhesions			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Polycystic ovaries			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Priapism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Uterine polyp			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulva cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Uterine prolapse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Adenomyosis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Atrophic vulvovaginitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Bartholin's cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Breast calcifications			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Breast enlargement			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cervical dysplasia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cervix inflammation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oligomenorrhoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Epididymal cyst			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Fibrocystic breast disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gynaecomastia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nipple pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Endometrial hyperplasia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pelvic congestion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peyronie's disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Premenstrual syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Prostatomegaly			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Testicular cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urogenital atrophy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaginal cyst			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaginal prolapse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Varicocele			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	3	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	4 / 234 (1.71%)	2 / 74 (2.70%)	1 / 76 (1.32%)
occurrences (all)	4	2	1
Choking			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bronchitis chronic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bronchiectasis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Atelectasis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	68 / 234 (29.06%)	10 / 74 (13.51%)	14 / 76 (18.42%)
occurrences (all)	88	10	21
Dry throat			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	2	0	1
Dyspnoea			
subjects affected / exposed	26 / 234 (11.11%)	4 / 74 (5.41%)	5 / 76 (6.58%)
occurrences (all)	43	6	7
Dyspnoea exertional			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	3	0	1
Haemoptysis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	1	0	2
Nasal obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	42 / 234 (17.95%)	8 / 74 (10.81%)	11 / 76 (14.47%)
occurrences (all)	52	9	11
Nasal cavity mass			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasal pruritus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pharyngeal erythema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pharyngeal swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Pleurisy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Productive cough			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	47 / 234 (20.09%)	7 / 74 (9.46%)	9 / 76 (11.84%)
occurrences (all)	56	9	12
Rhinitis allergic			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Respiratory tract congestion			



subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pulmonary mass			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	3	1	0
Pulmonary fibrosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pulmonary congestion			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	0	1	2
Rhinorrhoea			
subjects affected / exposed	43 / 234 (18.38%)	6 / 74 (8.11%)	8 / 76 (10.53%)
occurrences (all)	54	6	14
Sinonasal obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Sinus pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Suffocation feeling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Throat irritation			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Vasomotor rhinitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Acute respiratory failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Allergic bronchitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aspiration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Increased viscosity of bronchial secretion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Asthmatic crisis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Emphysema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0

Increased bronchial secretion subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Asthma exercise induced subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Laryngeal leukoplakia subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Laryngeal oedema subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Laryngitis allergic subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Lung consolidation subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Lung disorder subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Oropharyngeal plaque subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Nasal oedema subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Nasal septum deviation subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Nasal turbinate hypertrophy subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Nasal ulcer subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0

Obstructive airways disorder subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Nasal inflammation subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Orthopnoea subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pharyngeal hypertrophy subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pleuritic pain subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pneumonia aspiration subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pneumonitis subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pulmonary artery dilatation subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Respiratory distress subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pulmonary oedema subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Pulmonary toxicity subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Rales subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0

Reflux laryngitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Respiratory arrest			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory gas exchange disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tracheal disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0

Vocal cord polyp subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Tonsillar erythema subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	2 / 234 (0.85%) 2	1 / 74 (1.35%) 1	2 / 76 (2.63%) 2
Abnormal dreams subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Aggression subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Anxiety disorder subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Attention deficit hyperactivity disorder subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	4 / 234 (1.71%) 5	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Depressed mood subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	2 / 234 (0.85%) 2	3 / 74 (4.05%) 3	0 / 76 (0.00%) 0
Obsessive-compulsive disorder subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Euphoric mood			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Post-traumatic stress disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Somatic symptom disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

Autism spectrum disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anger			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Alcoholism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Alcohol abuse			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Agitation			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Bipolar disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Borderline personality disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Claustrophobia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Drug abuse			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Drug use disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Acute stress disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0



Grief reaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hallucinations, mixed			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mania			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Nervousness			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Panic disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Persistent complex bereavement disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Rapid eye movement sleep behaviour disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sleep terror			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device malfunction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Device occlusion			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Device loosening			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Device breakage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Device physical property issue			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cholecystitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cholelithiasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Hepatic steatosis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	2	0	1
Nonalcoholic fatty liver disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatic fibrosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cholecystitis chronic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bile duct stone			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

Biliary dyskinesia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Biliary obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatic cirrhosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hepatic cyst			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hepatic cytolysis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatosplenomegaly			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyperplastic cholecystopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	2	0
Blood cholesterol increased			
subjects affected / exposed	5 / 234 (2.14%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	5	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Blood glucose fluctuation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Blood potassium decreased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Blood potassium increased			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood pressure diastolic increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	3 / 234 (1.28%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	3	1	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood testosterone decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood urine present			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Coagulation test abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Cardiac murmur			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Cortisol decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Heart rate increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
International normalised ratio abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Liver function test abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Monocyte count increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mean cell volume decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Protein urine present			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Red blood cell count increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Smear cervix abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Reticulocyte count decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory rate decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Urine analysis abnormal			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Weight increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aortic bruit			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood folate decreased			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coagulation factor increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chlamydia test positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Carbohydrate antigen 19-9 increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Blood thyroid stimulating hormone decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood thrombin increased			
subjects affected / exposed	3 / 234 (1.28%)	3 / 74 (4.05%)	0 / 76 (0.00%)
occurrences (all)	3	3	0
Blood glucose abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood iron decreased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

Body temperature decreased subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Low density lipoprotein increased subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	1 / 74 (1.35%) 1	0 / 76 (0.00%) 0
Lipids increased subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Laboratory test abnormal subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Haematocrit increased subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Glucose urine present subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Gamma-glutamyltransferase abnormal subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Electrocardiogram repolarisation abnormality subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Culture urine positive subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Crystal urine present			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mycoplasma test positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Creatinine renal clearance increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Norovirus test positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neisseria test positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	2	1	0
Urine output decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urinary casts			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Transferrin saturation increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Streptococcus test positive subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Reticulocyte count increased subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Respiratory rate increased subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
White blood cells urine subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
HIV test positive subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Fibrin D dimer increased subjects affected / exposed occurrences (all)	2 / 234 (0.85%) 2	4 / 74 (5.41%) 4	0 / 76 (0.00%) 0
Electrocardiogram T wave inversion subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	1 / 74 (1.35%) 1	1 / 76 (1.32%) 1
Electrocardiogram T wave amplitude decreased subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Electrocardiogram T wave abnormal subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	1 / 76 (1.32%) 1
Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Electrocardiogram P wave biphasic			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
ECG signs of ventricular hypertrophy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coagulation factor VIII level increased			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Blood HIV RNA increased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anti factor VIII antibody increased			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Vitamin B12 decreased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vitamin B1 decreased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Troponin I increased			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	2	0	2
Thrombin-antithrombin III complex increased			
subjects affected / exposed	2 / 234 (0.85%)	2 / 74 (2.70%)	1 / 76 (1.32%)
occurrences (all)	3	2	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
QRS axis abnormal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Anaesthetic complication			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arteriovenous fistula site complication			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Arthropod sting			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Back injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Complications of transplant surgery			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chest injury			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Arteriovenous fistula aneurysm			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	2	1	0
Epicondylitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Eyelid contusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Foreign body in eye			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Femur fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	2	1	0
Foreign body			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Foreign body in ear			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fall			

subjects affected / exposed	9 / 234 (3.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	9	1	0
Hand fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hip fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injection related reaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	3 / 234 (1.28%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	3	1	0
Lip injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lower limb fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			



subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Muscle rupture			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Neck injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Patella fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	2	0	2
Periorbital haematoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Procedural pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pelvic bone injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	0	1	1
Skin abrasion			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	0	0	2
Skin laceration			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Skull fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Splinter			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Upper limb fracture			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Stress fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Stoma site haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vascular access site haemorrhage			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chemical burns of eye			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Accident at work			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Alcohol poisoning			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Arteriovenous fistula occlusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arteriovenous fistula site haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Avulsion fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Barotitis media			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Accident			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haemodialysis complication			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Heat exhaustion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

Clavicle fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Corneal abrasion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Craniocerebral injury			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Gun shot wound			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Facial bones fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Forearm fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Graft complication			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Extradural haematoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Hyphaema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Incisional hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ligament injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Poisoning			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Multiple fractures			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Muscle injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nerve injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Osteochondral fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Overdose			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Median nerve injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Post concussion syndrome subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Post procedural complication subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Post procedural constipation subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Post procedural diarrhoea subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Post-traumatic neck syndrome subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Postoperative delirium subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Spinal column injury subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Radiation pneumonitis subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Second degree chemical burn of skin subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Seroma subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Skin injury subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Skin wound subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0

Procedural nausea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Stab wound			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Stomal hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tendon injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tibia fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Traumatic ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ulnar nerve injury			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal injury			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arteriovenous malformation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thalassaemia beta			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermoid cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Type V hyperlipidaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Angina unstable			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Atrial fibrillation			
subjects affected / exposed	2 / 234 (0.85%)	2 / 74 (2.70%)	3 / 76 (3.95%)
occurrences (all)	2	2	3
Bradycardia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bundle branch block left			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coronary artery disease			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	2	1	2
Cardiomyopathy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	5 / 234 (2.14%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	5	0	0
Left ventricular failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sinus arrhythmia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	2	1	0
Atrioventricular block first degree			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	2	0	1
Atrial flutter			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Atrial enlargement			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aortic valve stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aortic valve sclerosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Acute myocardial infarction			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Acute left ventricular failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Acute coronary syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cardiac failure acute			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cardiac failure congestive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chronotropic incompetence			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Diastolic dysfunction			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coronary artery stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bundle branch block right			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Bifascicular block			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Cardiac failure			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Coronary artery occlusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intracardiac thrombus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Left atrial enlargement			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Left ventricular dysfunction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Mitral valve stenosis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myocardial infarction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Ventricular hypokinesia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ventricular hypertrophy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Ventricular fibrillation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pericardial effusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myocarditis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Ageusia			
subjects affected / exposed	8 / 234 (3.42%)	3 / 74 (4.05%)	1 / 76 (1.32%)
occurrences (all)	8	3	1
Amnesia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anosmia			
subjects affected / exposed	7 / 234 (2.99%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	8	1	0
Aphasia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Balance disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Clonus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bell's palsy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Carotid artery occlusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cervical radiculopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Dysarthria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	5 / 234 (2.14%)	3 / 74 (4.05%)	1 / 76 (1.32%)
occurrences (all)	5	3	1
Depressed level of consciousness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dementia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Encephalopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyposmia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	52 / 234 (22.22%)	8 / 74 (10.81%)	7 / 76 (9.21%)
occurrences (all)	64	9	11
Head discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Essential tremor			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intercostal neuralgia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intraneural cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Lethargy			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Loss of consciousness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 234 (0.00%)	2 / 74 (2.70%)	0 / 76 (0.00%)
occurrences (all)	0	2	0
Movement disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nerve compression			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Neuralgia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1

Post-traumatic headache			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	1	1	1
Sciatica			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Seizure			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Sinus headache			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Tension headache			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0



Altered state of consciousness subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Amyotrophic lateral sclerosis subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Carpal tunnel syndrome subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Carotid artery thrombosis subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Cerebral infarction subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Cerebral congestion subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Cerebral atrophy subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Cerebral artery occlusion subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Cerebral arteriosclerosis subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Cerebellar infarction subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Central pain syndrome subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0

Axonal neuropathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Carotid arteriosclerosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Carotid artery stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cubital tunnel syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cranial nerve disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Complex regional pain syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Cluster headache			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Diabetic neuropathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cervicogenic headache			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cerebral small vessel ischaemic disease			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cerebral microangiopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cerebral ischaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fine motor skill dysfunction			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Facial paresis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Dizziness postural			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Metabolic encephalopathy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Mental impairment			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lumbar radiculopathy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Leukoencephalopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lacunar infarction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Radicular pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Polyneuropathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Piriformis syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Muscle contractions involuntary			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Peripheral nerve lesion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Parkinson's disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Osmotic demyelination syndrome			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myelopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peroneal nerve palsy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vascular dementia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Transient global amnesia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Spinal claudication			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Speech disorder			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	1	1	2
Increased tendency to bruise			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Neutrophilia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	2	0	1
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Normocytic anaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Polycythaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			

subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Deficiency anaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood loss anaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Anaemia of chronic disease			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Bone marrow oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hilar lymphadenopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyperleukocytosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Hypochromic anaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Macrocytosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Microcytic anaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Deafness unilateral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vertigo			



subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Tinnitus			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Inner ear inflammation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Sudden hearing loss			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Presbycusis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haematotympanum			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eustachian tube dysfunction			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ear canal erythema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Deafness bilateral			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Superior semicircular canal dehiscence			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vertigo positional			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			

subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Dry age-related macular degeneration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye allergy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Periorbital pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Scleritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Age-related macular degeneration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Asthenopia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Astigmatism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chalazion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermatochalasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Diabetic retinopathy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Erythema of eyelid			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Macular degeneration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Macular fibrosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Macular oedema			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Myopia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ocular hypertension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ophthalmoplegia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Diabetic retinal oedema			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

Vitreous detachment			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vitreous adhesions			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Uveitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Orbital oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Retinal detachment			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Pterygium			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Presbyopia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Posterior capsule opacification			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Retinal tear			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	7 / 234 (2.99%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	7	1	0
Abdominal rigidity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	1	1	2
Abdominal pain lower			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Abdominal tenderness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anal polyp			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Change of bowel habit			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Dental caries			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	5 / 234 (2.14%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	5	1	1
Colitis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Diarrhoea			
subjects affected / exposed	23 / 234 (9.83%)	3 / 74 (4.05%)	5 / 76 (6.58%)
occurrences (all)	26	3	5
Dry mouth			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Diverticulum intestinal			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Diverticulum			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	2	0	2
Dyspepsia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Faeces discoloured			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Faeces soft			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gingival disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 234 (2.14%)	2 / 74 (2.70%)	1 / 76 (1.32%)
occurrences (all)	5	2	1
Gastritis			
subjects affected / exposed	1 / 234 (0.43%)	2 / 74 (2.70%)	4 / 76 (5.26%)
occurrences (all)	1	2	4
Gastrointestinal hypermotility			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hiatus hernia			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Haemorrhoids			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Oral mucosal blistering			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	14 / 234 (5.98%)	6 / 74 (8.11%)	8 / 76 (10.53%)
occurrences (all)	16	6	11
Mouth ulceration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mouth haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lip disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Salivary gland enlargement			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peptic ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pancreatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral mucosal eruption			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Swollen tongue			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tongue disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tongue discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	10 / 234 (4.27%)	3 / 74 (4.05%)	2 / 76 (2.63%)
occurrences (all)	10	3	3
Toothache			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal mass			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anal skin tags			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anogenital dysplasia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Chronic gastritis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Apical granuloma			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Bile acid malabsorption			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bowel movement irregularity			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anorectal disorder			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Colitis ulcerative			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Crohn's disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Diaphragmatic hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Duodenitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dyskinesia oesophageal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Colitis microscopic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Functional gastrointestinal disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gastric disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coeliac disease			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastritis alcoholic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastritis erosive			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal mucosa hyperaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Giant cell epulis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Glossodynia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haematemesis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Inflammatory bowel disease			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia strangulated			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Large intestinal stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Large intestinal ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oesophageal motility disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oesophageal dilatation			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oesophageal disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oesophageal spasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oesophageal stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pancreatic failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pancreatic mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pancreatic steatosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Salivary gland disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Plicated tongue			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Proctitis			



subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rectal polyp			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Pancreatitis chronic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Salivary gland mucocoele			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sigmoid mesocolon hernia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Small intestinal obstruction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Submaxillary gland enlargement			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tongue discolouration			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tongue geographic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth disorder			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth loss			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Trichoglossia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tongue erythema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Uvulitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Dermatitis			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	1	2	1

Diabetic wound			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Angioedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Erythema			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Dry skin			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lichen sclerosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Miliaria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Macule			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	2	1	1
Pityriasis rosea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	0	1	3
Rash erythematous			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Rash pruritic			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin striae			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Granuloma annulare			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Hand dermatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis follicularis et parafollicularis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lipodystrophy acquired			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Penile ulceration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Photodermatosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hirsutism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pigmentation disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pruritus allergic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Purpura			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Purpura senile			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sensitive skin			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin oedema			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin plaque			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Crystalluria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	1	3	2
Chromaturia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Calculus bladder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Bladder spasm			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bladder cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Micturition disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	2 / 234 (0.85%)	2 / 74 (2.70%)	0 / 76 (0.00%)
occurrences (all)	2	2	0
Dysuria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Nocturia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0



Pollakiuria			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Renal colic			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Renal failure			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Renal impairment			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0
Stress urinary incontinence			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ureterolithiasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urethral meatus stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urge incontinence			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Urinary retention			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Urinary incontinence			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

End stage renal disease subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Glycosuria subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Lupus nephritis subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Microalbuminuria subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Micturition urgency subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Stag horn calculus subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Bladder outlet obstruction subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Urinary tract obstruction subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Urethral stenosis subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Endocrine disorders			
Autoimmune thyroiditis subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Hypogonadism			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Goitre			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Addison's disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Adrenomegaly			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Thyroid mass			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Hyperparathyroidism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypothalamo-pituitary disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pituitary cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Primary hypogonadism			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Thyroid atrophy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Androgen deficiency			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue			

disorders			
Ankle deformity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	16 / 234 (6.84%)	2 / 74 (2.70%)	3 / 76 (3.95%)
occurrences (all)	19	2	3
Bursitis			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0
Back pain			
subjects affected / exposed	9 / 234 (3.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	9	1	0
Arthritis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Dupuytren's contracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cervical spinal stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Femoroacetabular impingement			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fibromyalgia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Flank pain			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Foot deformity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint hyperextension			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Muscle tightness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	2	1	1
Limb discomfort			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	4 / 234 (1.71%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	5	0	0
Musculoskeletal discomfort			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	28 / 234 (11.97%)	2 / 74 (2.70%)	6 / 76 (7.89%)
occurrences (all)	34	2	7
Neck pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	7 / 234 (2.99%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	7	1	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Osteoporotic fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	5 / 234 (2.14%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	5	0	1
Psoriatic arthropathy			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Periarthritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			

subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Polyarthrititis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Sacroiliitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Synovial cyst			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Tendon pain			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Trigger finger			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ankylosing spondylitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Arthropathy			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Chondrocalcinosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chondromalacia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Diastasis recti abdominis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Enostosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Enthesopathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc displacement			



subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Exostosis of jaw			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Facet joint syndrome			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Haemarthrosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc compression			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc disorder			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint ankylosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint contracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint noise			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Myositis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Limb mass			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Mobility decreased			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Morphoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Muscle atrophy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pelvic deformity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Scapholunate dissociation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Scoliosis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Sjogren's syndrome			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Spinal stenosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Spondylitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Spondylolisthesis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Synovitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tendon calcification			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Soft tissue mass			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tenosynovitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tenosynovitis stenosans			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vertebral foraminal stenosis			

subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anal chlamydia infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arthritis bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Chlamydial infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0

Diverticulitis			
subjects affected / exposed	3 / 234 (1.28%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	3	1	0
Cystitis			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	2	1	0
Cystitis escherichia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dermatophytosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Eye abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Febrile infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Folliculitis			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	3	0	1
Fungal infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gingival abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	4 / 234 (1.71%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	4	1	0
Hordeolum			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gonorrhoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Infected dermal cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	3 / 76 (3.95%)
occurrences (all)	2	0	3
Laryngitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	7 / 234 (2.99%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	9	0	0
Nail bed infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	12 / 234 (5.13%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	12	0	0
Onychomycosis			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	0	1	1
Paronychia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Otitis media			

subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Periodontitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Post procedural pneumonia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pustule			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			



subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Pilonidal cyst			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	2 / 76 (2.63%)
occurrences (all)	3	0	2
Sinusitis bacterial			
subjects affected / exposed	1 / 234 (0.43%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	1	1	0
Skin bacterial infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Secondary syphilis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	4	0	0
Respiratory tract infection viral			

subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Respiratory tract infection			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	8 / 234 (3.42%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	9	1	2
Staphylococcal skin infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	8 / 234 (3.42%)	2 / 74 (2.70%)	2 / 76 (2.63%)
occurrences (all)	9	3	3
Tooth infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	2	0	1
Tonsillitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Syphilis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			

subjects affected / exposed	13 / 234 (5.56%)	6 / 74 (8.11%)	6 / 76 (7.89%)
occurrences (all)	13	6	7
Vaginal cellulitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0
Viral rhinitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Viraemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abdominal abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Abscess limb			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Anal candidiasis			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Balanitis candida			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Arteriovenous graft site infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Atypical pneumonia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacterial disease carrier			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Appendicitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Body tinea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Bronchitis bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Candida infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Coccidioidomycosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cytomegalovirus infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dacryocanaliculitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dengue haemorrhagic fever			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Cervicitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Erysipelas			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Fungaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0

Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Genitourinary chlamydia infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Gonococcal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Groin infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Haemophilus infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infected bite			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0

Infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infectious pleural effusion			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Intervertebral discitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Klebsiella infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lung abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lyme disease			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Lymphangitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Medical device site abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal gonococcal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Mucormycosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nasal vestibulitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Orchitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis			



subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Papilloma viral infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Parotitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pertussis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pneumonia bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pneumonia klebsiella			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Post procedural infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Proctitis gonococcal			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis acute			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory tract chlamydial infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Root canal infection			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Sialoadenitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Sinusitis fungal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection bacterial			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Staphylococcal abscess			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Systemic candida			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tinea cruris			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Tinea infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Trichomoniasis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Spirochaetal infection			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urethritis gonococcal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Viral diarrhoea			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Asymptomatic COVID-19			
subjects affected / exposed	9 / 234 (3.85%)	1 / 74 (1.35%)	3 / 76 (3.95%)
occurrences (all)	9	1	3
Post-acute COVID-19 syndrome			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	3	0	0
Hepatitis C			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
HIV peripheral neuropathy			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

COVID-19 pneumonia subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
COVID-19 subjects affected / exposed occurrences (all)	64 / 234 (27.35%) 69	12 / 74 (16.22%) 12	13 / 76 (17.11%) 15
Suspected COVID-19 subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	1 / 76 (1.32%) 1
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	14 / 234 (5.98%) 14	3 / 74 (4.05%) 3	1 / 76 (1.32%) 1
Hyperglycaemia subjects affected / exposed occurrences (all)	2 / 234 (0.85%) 2	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	3 / 234 (1.28%) 3	0 / 74 (0.00%) 0	2 / 76 (2.63%) 2
Diabetes mellitus subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	1 / 74 (1.35%) 1	4 / 76 (5.26%) 4
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	1 / 234 (0.43%) 1	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Hypercholesterolaemia subjects affected / exposed occurrences (all)	3 / 234 (1.28%) 3	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Glucose tolerance impaired subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	0 / 74 (0.00%) 0	0 / 76 (0.00%) 0
Gout subjects affected / exposed occurrences (all)	0 / 234 (0.00%) 0	2 / 74 (2.70%) 3	1 / 76 (1.32%) 1
Hypercalcaemia			

subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Folate deficiency			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	0	1	2
Hypertriglyceridaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	2 / 234 (0.85%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	2	1	1
Hypovitaminosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	4 / 234 (1.71%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	5	1	2
Obesity			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	2 / 76 (2.63%)
occurrences (all)	0	1	2
Calciphylaxis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Fluid overload			
subjects affected / exposed	0 / 234 (0.00%)	1 / 74 (1.35%)	1 / 76 (1.32%)
occurrences (all)	0	1	1
Histamine intolerance			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	3 / 234 (1.28%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	3	0	1
Hypophagia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hypovolaemia			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			

subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	2	0	1
Metabolic acidosis			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	0	0	1
Metabolic syndrome			
subjects affected / exposed	0 / 234 (0.00%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	1 / 76 (1.32%)
occurrences (all)	1	0	1
Vitamin B12 deficiency			
subjects affected / exposed	1 / 234 (0.43%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
Vitamin B complex deficiency			
subjects affected / exposed	2 / 234 (0.85%)	0 / 74 (0.00%)	0 / 76 (0.00%)
occurrences (all)	2	0	0

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 October 2020	Synopsis and Section 4.1 (Overall Design), and Section 7.4 (Study Suspension/Early Termination): Addition of wording that if the study is suspended or the decision is made not to proceed from Stage 1 to Stage 2. Section 5.1 (Inclusion Criteria), Inclusion Criterion 2: Expansion of the criterion to clarify definition of participants who are in an immunocompromised state to include those with solid organ transplant, blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immunosuppressive medicines.
13 November 2020	Changes have been made to the protocol in response to health authority comments, which requested the inclusion of increased safety monitoring with particular emphasis on potential hypersensitivity reactions immediately after IMP administration. As of 14 September 2020 no hypersensitivity reactions have been observed in the Phase I study. Health authority comments also recommended considering testing the null hypothesis of no difference between treatment groups without a specific lower bound to demonstrate statistical superiority over placebo.
21 December 2020	<p>Due to the ongoing unprecedented situation caused by the COVID-19 pandemic, the criterion excluding AstraZeneca employees has been amended to allow employees and their family members not involved in AZD7442 development to participate in this study, if otherwise eligible. Participants will be permitted to enter the study if they have previously received immunoglobulins, including mAbs that have been approved for an indication other than COVID-19. AZD7442 and other mAbs will not be co-administered. Monoclonal antibodies approved for indications other than COVID-19 that have been administered prior to consideration for this trial will not disqualify a participant from participation in this study.</p> <p>After randomization, they are permitted at any point during the study other than the day of IMP administration.</p> <p>Allowing the use of other mAbs during the study does not appear to pose any safety risk. AZ mAbs bind specifically to the receptor binding domain of the Spike protein of SAR-CoV-2, but not to human targets. Published mAb-mAb interaction studies are rare.</p> <p>One clinical study of co-administration of pertuzumab and trastuzumab + docetaxel via separate infusions, which each bind to different epitopes on the HER2 receptor, illustrated that the PK of one mAb is not affected by the administration of the other (Cortés et al 2013). Therefore, it is not expected that the action of AZD7442 will be affected by the presence of another mAb, including its PK parameters, clearance and elimination. Any potential impact on AZD7442 PK will be examined for any participants that have received a commercial mAb.</p>



12 February 2021	<p>The study had been initially sized to allow for a more detailed assessment of efficacy, including greater precision in subpopulations, and therefore had &gt;95% power to demonstrate that the lower bound of the 2-sided 95% CI for efficacy is greater than 0 (assuming an observed annualized attack rate of 3% in the placebo group and true efficacy of 80%). Efficacious vaccines against SARS-CoV-2 are being deployed on a mass scale in the participating countries and a higher proportion of participants in the study are electing to become unblinded to consider vaccination for COVID-19 than was originally expected. To reduce the potential impact of unblinding on the study's ability to robustly quantify efficacy, the primary analysis will be conducted at an earlier time point and the strategy for handling intercurrent events for the primary efficacy endpoint will be changed from a treatment policy strategy to a while on treatment strategy, which was previously a sensitivity analyses. The amended study design will have ~90% power to demonstrate that the lower bound of the 2-sided 95% CI for efficacy is greater than 0 with the same assumptions. The study is being conducted using AZD7442 material derived from a non-clonal pool of cells from a pooled batch (separately manufactured pools for AZD8895 and AZD1061). Clonal material from a single production cell line that forms a Master Cell bank will be used as the source of the commercial supply. The addition of a subset of participants in study, to be treated with the clonal material, will provide clinical data on the clonal material in the prophylaxis population. To incorporate health authority feedback, a subset of additional 150 participants will be included to receive clonal IMP or placebo in a 2:1 ratio. The sample size has been increased from 5000 to 5150 participants. The clonal material subset will be enrolled in the US</p>
18 March 2021	<p>Highly efficacious vaccines against SARS-CoV-2 are being deployed on a mass scale in the participating countries and a higher proportion of participants in the study are electing to become unblinded to consider vaccination for COVID-19 than was originally expected. In order to further reduce the potential impact of unblinding on the study's ability to robustly quantify efficacy, the primary analysis will be conducted 30 days after the 24th primary endpoint event has occurred. This period allows sufficient time for absorption and systemic exposure of AZD7442 administered IM and any other events occurring during this time interval will also be evaluated. Furthermore, to remove recruitment restrictions the stratification caps have been removed from Cohorts 1 and 2. To provide data on AZD7442 for 5 half-lives, the study has been extended to 15 months allowing a safety assessment via a phone call and an optional serum sample for PK, ADA, and nAb to be added at Day 457. Study endpoints have been adjusted accordingly.</p>
07 April 2021	<p>Highly efficacious vaccines against SARS-CoV-2 are being deployed on a mass scale in the participating countries and a higher proportion of participants in the study are electing to become unblinded to consider vaccination for COVID-19 than was originally expected. The process of vaccination has accelerated further in the past 2 to 3 weeks. Consequently, the probability to observe primary endpoint events will diminish with increasing vaccination of the enrolled population. Modelling results suggest that the unblinding rate is increasing over time and that by the time 30% unblinding is reached, the annualized attack rate will have begun to decelerate and will further decline in proportion to the unblinding. This puts the delivery of the study at significant risk. In order to reduce the potential impact of unblinding on the study's ability to robustly quantify placebo-controlled efficacy, the primary analysis has been adjusted to be conducted after approximately 24 primary endpoint events have been confirmed or 30% of study participants have become unblinded, whichever occurs first. Taking the earlier of these 2 scenarios will avoid an unnecessary delay to reporting trial results irrespective of additional unblinding acceleration. Additionally, the 30-day observation period has been removed as the current pace of unblinding makes this addition untenable. If the unblinding rate does not accelerate beyond the predicted, then the study is likely to observe the 24 primary endpoint events (congruent with the previous version of the protocol).</p>

29 June 2021	<p>The strategy for handling intercurrent events for the primary efficacy endpoint is to censor participants who become unblinded to treatment assignment to consider vaccination against COVID-19 at the date of unblinding, regardless of whether they subsequently receive a COVID-19 vaccine/preventive product. While the impact of unblinding on the interpretation of the primary endpoint is unknown, receipt of vaccine is expected to affect the interpretation since efficacy of COVID-19 vaccines has been demonstrated. Therefore, an additional estimand strategy, in which the intercurrent event is receipt of a COVID-19 vaccine, has been included as a key supportive analysis of the primary endpoint. The level of unblinding at the primary analysis will be approximately 30% and is likely to increase as the study continues. Since participants who become unblinded to treatment assignment are censored at the date of unblinding for the key secondary objective to estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of COVID-19 through Day 366, it is unlikely to yield different results from that of the primary analysis. Therefore, this secondary objective will be changed to an exploratory objective and the endpoint of incidence of the first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring after dosing with IMP through Day 366 removed from the multiple testing hierarchy. Instead, the important secondary objective to estimate the efficacy of a single IM dose of AZD7442 compared to placebo for the prevention of SARS-CoV-2 infection and endpoint of incidence of participants who have a post-treatment response for SARS-CoV-2 nucleocapsid antibodies will be included in the multiple testing hierarchy</p>
26 July 2021	<p>In response to health authority feedback, the following changes have been made: The primary analysis of the primary endpoint will include all participants who were hospitalized due to COVID-19, regardless of severity. Previously, only participants who were hospitalized due to COVID-19 that met the protocol-defined criteria for severe were included.</p> <p>The key supportive analysis of the primary endpoint, in which participants who receive a COVID-19 vaccine or preventive product are censored 14 days following receipt (referred to as "vaccine-efficacy censor" estimand), has been removed.</p> <p>A key supportive analysis of the primary endpoint, in which the endpoint is defined as the first case of SARS-CoV-2 RT-PCR-positive symptomatic illness or death from any cause post dose of IMP and prior to Day 183, has been added and included in the hierarchical testing strategy.</p> <p>In addition, an independent Morbidity Adjudication Committee will be constituted to provide an independent, external, systematic, and unbiased assessment of blinded data to evaluate whether the causes of death for participants are considered COVID-19 associated.</p> <p>Only adjudicated deaths will be included in efficacy endpoints. All fatal events will be further assessed as part of safety evaluation. Further details of this adjudication will be provided in a separate Morbidity Adjudication Committee Charter.</p> <p>A clarification that all participants who become unblinded to treatment (regardless of the reason) will be considered as intercurrent events rather than only those who became unblinded to consider vaccination for COVID-19.</p>
01 December 2021	<p>An addendum has been added to include a sub-study to the Phase III PROVENT study: 'A Phase III Multi-center, Open-label Sub-study in Adults to Assess the Safety, PK, and Immunogenicity of Repeat Doses of AZD7442, a Combination Product of Two Monoclonal Antibodies (AZD8895 and AZD1061) (The PROVENT Repeat Dose Sub-study)'(D8850C002A01). The sub-study will assess the safety, PK, and immunogenicity of repeat doses of AZD7442 in participants currently enrolled in the PROVENT study who may benefit from a repeat dose of AZD7442. This study will investigate whether additional doses of AZD7442 have an appropriate safety profile in this vulnerable population. Pharmacokinetic data will also be generated to evaluate whether repeat dosing can maintain serum levels associated with protection against COVID-19. Participants at a sub-set of active PROVENT parent study sites in participating countries will be invited to enroll in this sub-study (N=500). The conduct of the parent study will not change for those participants who are not included in the sub-study.</p>

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
30 March 2023	On 30 March 2023, the FDA requested AstraZeneca to stop dosing adult participants in the US until the informed consent form had been updated to reflect the new benefit-risk assessment as, given that AZD7442 (EVUSHELD™) was not active against > 99% of the circulating SARS-CoV-2 variants in the US at that time, the benefit-risk assessment may not be favorable. AstraZeneca made the decision to stop dosing globally in all ongoing EVUSHELD studies including the PROVENT Sub-study and updated the informed consent form detailing the FDA guidance and decision to stop dosing globally. All actively enrolled participants were reconsented and remained in the study to complete visits/assessments (except those related to monitoring of IMP administration) for safety for at least 6 months after the last IMP administration.	-

Notes:

### Limitations and caveats

None reported