



## Clinical trial results:

### A Randomized, Double-Blind, Multi-Center, Parallel Group Study to Assess the Efficacy and Safety of PT010 Relative to PT003 and PT009 on COPD Exacerbations over a 52-Week Treatment Period in Subjects With Moderate to Very Severe COPD

#### Summary

EudraCT number	2014-005671-92
Trial protocol	NL AT DE BE PL HU CZ SE ES IT
Global end of trial date	26 July 2019

#### Results information

Result version number	v1 (current)
This version publication date	01 October 2020
First version publication date	01 October 2020

#### Trial information

##### Trial identification

Sponsor protocol code	PT010005
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02465567
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Pearl Therapeutics Inc
Sponsor organisation address	200 Cardinal Way, Redwood City, California, United States, 94063
Public contact	Pearl Therapeutics Inc, Pearl Therapeutics Inc, 1 18772409479, information.center@astrazeneca.com
Scientific contact	Pearl Therapeutics Inc, Pearl Therapeutics Inc, 1 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	26 July 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 July 2019
Global end of trial reached?	Yes
Global end of trial date	26 July 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

Efficacy and Safety

Protection of trial subjects:

All subjects were put on active treatment for the duration of the study. Ventolin HFA was provided throughout the study for subjects to take as needed for relief of symptoms. Antibiotics and corticosteroids were allowed for use to treat COPD exacerbation during the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 July 2015
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	Argentina: 802
Country: Number of subjects enrolled	Australia: 68
Country: Number of subjects enrolled	Austria: 272
Country: Number of subjects enrolled	Belgium: 61
Country: Number of subjects enrolled	Canada: 171
Country: Number of subjects enrolled	Chile: 274
Country: Number of subjects enrolled	China: 533
Country: Number of subjects enrolled	Czech Republic: 105
Country: Number of subjects enrolled	France: 28
Country: Number of subjects enrolled	Germany: 1198
Country: Number of subjects enrolled	Hungary: 97
Country: Number of subjects enrolled	Italy: 40
Country: Number of subjects enrolled	Japan: 7
Country: Number of subjects enrolled	Mexico: 52
Country: Number of subjects enrolled	Netherlands: 95
Country: Number of subjects enrolled	New Zealand: 92
Country: Number of subjects enrolled	Peru: 191
Country: Number of subjects enrolled	Poland: 101
Country: Number of subjects enrolled	Russian Federation: 95
Country: Number of subjects enrolled	Serbia: 463
Country: Number of subjects enrolled	South Africa: 280

Country: Number of subjects enrolled	Spain: 209
Country: Number of subjects enrolled	Sweden: 35
Country: Number of subjects enrolled	Taiwan: 47
Country: Number of subjects enrolled	United Kingdom: 195
Country: Number of subjects enrolled	United States: 3077
Worldwide total number of subjects	8588
EEA total number of subjects	2436

Notes:

<b>Subjects enrolled per age group</b>	
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)	4117
From 65 to 84 years	4471
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

This study was conducted in 26 countries between July 2015 and July 2019.

### Pre-assignment

Screening details:

Subjects who successfully complete the Screening Period will then be randomized in a 1:1:1:1 scheme to BGF MDI 320/14.4/9.6 µg BID, BGF MDI 160/14.4/9.6 µg BID, BFF MDI 320/9.6 µg BID, or GFF MDI 14.4/9.6 µg BID, respectively.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	BGF MDI 320/14.4/9.6 µg

Arm description:

Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation

Arm type	Experimental
Investigational medicinal product name	Budesonide, Glycopyrronium, and Formoterol Fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pressurised inhalation, suspension
Routes of administration	Inhalation use

Dosage and administration details:

Metered Dose Inhalation 320/14.4/9.6 µg

<b>Arm title</b>	BGF MDI 160/14.4/9.6 µg
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Arm description:

Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation

Arm type	Experimental
Investigational medicinal product name	Budesonide, Glycopyrronium, and Formoterol Fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pressurised inhalation, suspension
Routes of administration	Inhalation use

Dosage and administration details:

Metered Dose Inhalation 160/14.4/9.6 µg

<b>Arm title</b>	GFF MDI 14.4/9.6 µg
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Arm description:

Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation

Arm type	Experimental
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Investigational medicinal product name	Glycopyrronium, and Formoterol Fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pressurised inhalation, suspension
Routes of administration	Inhalation use
Dosage and administration details:	
Metered Dose Inhalation 14.4/9.6 µg	
<b>Arm title</b>	BFF MDI 320/9.6 µg

Arm description:

Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation

Arm type	Experimental
Investigational medicinal product name	Budesonide, , and Formoterol Fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Pressurised inhalation, suspension
Routes of administration	Inhalation use

Dosage and administration details:

Metered Dose Inhalation 320/14.4/9.6 µg

<b>Number of subjects in period 1</b>	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg
Started	2157	2137	2143
Completed	1708	1713	1580
Not completed	449	424	563
Administrative Reasons	12	9	11
Consent withdrawn by subject	104	94	123
Physician decision	23	33	38
randomized but not treated	1	5	4
Major Protocol Deviation	24	26	22
Adverse event, non-fatal	118	113	147
Protocol Specified Criteria	20	10	9
Enrolled in more than one study	18	11	19
Missing PI Signature	1	-	-
Lost to follow-up	25	21	19
Lack of efficacy	103	102	171

<b>Number of subjects in period 1</b>	BFF MDI 320/9.6 µg
Started	2151
Completed	1643
Not completed	508
Administrative Reasons	5
Consent withdrawn by subject	130
Physician decision	28

randomized but not treated	5
Major Protocol Deviation	25
Adverse event, non-fatal	138
Protocol Specified Criteria	12
Enrolled in more than one study	15
Missing PI Signature	-
Lost to follow-up	15
Lack of efficacy	135

## Baseline characteristics

### Reporting groups

Reporting group title	BGF MDI 320/14.4/9.6 µg
Reporting group description: Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	
Reporting group title	BGF MDI 160/14.4/9.6 µg
Reporting group description: Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	
Reporting group title	GFF MDI 14.4/9.6 µg
Reporting group description: Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	
Reporting group title	BFF MDI 320/9.6 µg
Reporting group description: Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	

Reporting group values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg
Number of subjects	2157	2137	2143
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1046	1038	1000
From 65-84 years	1111	1099	1143
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	64.6	64.6	64.8
standard deviation	± 7.6	± 7.6	± 7.6
Sex: Female, Male Units: Participants			
Female	887	831	887
Male	1270	1306	1256
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	33	40	30
Asian	162	166	157
Native Hawaiian or Other Pacific Islander	2	0	0
Black or African American	80	92	77
White	1836	1795	1829
More than one race	0	0	0
Unknown or Not Reported	44	44	50

Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	413	403	442
Not Hispanic or Latino	1697	1686	1656
Unknown or Not Reported	47	48	45

<b>Reporting group values</b>	BFF MDI 320/9.6 µg	Total	
Number of subjects	2151	8588	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	1033	4117	
From 65-84 years	1118	4471	
85 years and over	0	0	
Age Continuous			
Units: Years			
arithmetic mean	64.6		
standard deviation	± 7.6	-	
Sex: Female, Male			
Units: Participants			
Female	861	3466	
Male	1290	5122	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	39	142	
Asian	166	651	
Native Hawaiian or Other Pacific Islander	0	2	
Black or African American	67	316	
White	1833	7293	
More than one race	0	0	
Unknown or Not Reported	46	184	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	411	1669	
Not Hispanic or Latino	1693	6732	
Unknown or Not Reported	47	187	



## End points

### End points reporting groups

Reporting group title	BGF MDI 320/14.4/9.6 µg
Reporting group description: Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	
Reporting group title	BGF MDI 160/14.4/9.6 µg
Reporting group description: Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	
Reporting group title	GFF MDI 14.4/9.6 µg
Reporting group description: Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	
Reporting group title	BFF MDI 320/9.6 µg
Reporting group description: Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation	

### Primary: Treatment rate ratio

End point title	Treatment rate ratio
End point description: Rate of moderate or severe COPD exacerbations	
End point type	Primary
End point timeframe: 52-week treatment period	

End point values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg	BFF MDI 320/9.6 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1026	1013	1056	1085
Units: adjusted rate ratio (comparisons)				
number (confidence interval 95%)				
BGF MDI 320/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.76 (0.69 to 0.83)	0.87 (0.79 to 0.95)
BGF MDI 160/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.75 (0.69 to 0.83)	0.86 (0.79 to 0.95)

### Statistical analyses

Statistical analysis title	Rate of moderate or severe COPD exacerbations
Comparison groups	BGF MDI 320/14.4/9.6 µg v BGF MDI 160/14.4/9.6 µg

Number of subjects included in analysis	2039
Analysis specification	Pre-specified
Analysis type	superiority
P-value	$\geq 0.9328$
Method	Mixed models analysis
Parameter estimate	Rate Ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.1
Variability estimate	Standard error of the mean
Dispersion value	0.048

<b>Statistical analysis title</b>	Rate of moderate or severe COPD exacerbations
Comparison groups	BGF MDI 320/14.4/9.6 µg v GFF MDI 14.4/9.6 µg
Number of subjects included in analysis	2082
Analysis specification	Pre-specified
Analysis type	superiority
P-value	$\geq 0$
Method	Mixed models analysis
Parameter estimate	Rate ratio
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	0.83
Variability estimate	Standard error of the mean
Dispersion value	0.036

<b>Statistical analysis title</b>	Rate of moderate or severe COPD exacerbations
Comparison groups	BGF MDI 320/14.4/9.6 µg v BFF MDI 320/9.6 µg
Number of subjects included in analysis	2111
Analysis specification	Pre-specified
Analysis type	superiority
P-value	$\geq 0.0027$
Method	Mixed models analysis
Parameter estimate	Rate Ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	0.95

Variability estimate	Standard error of the mean
Dispersion value	0.041

### Secondary: Time to first moderate or severe COPD exacerbation

End point title	Time to first moderate or severe COPD exacerbation
End point description:	Time to first moderate or severe COPD exacerbation
End point type	Secondary
End point timeframe:	52 Weeks

End point values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg	BFF MDI 320/9.6 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1026	1013	1056	1085
Units: Months				
least squares mean (confidence interval 95%)				
BGF MDI 320/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.88 (0.0807 to 0.959)	0.887 (0.814 to 0.966)
BGF MDI 160/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.866 (0.794 to 0.944)	0.873 (0.801 to 0.951)

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from baseline in average daily rescue Ventolin HFA use

End point title	Change from baseline in average daily rescue Ventolin HFA use
End point description:	Change from baseline in average daily rescue Ventolin HFA use over 24 weeks
End point type	Secondary
End point timeframe:	24 Weeks

End point values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg	BFF MDI 320/9.6 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1425	1389	1387	1426
Units: Puffs				
least squares mean (confidence interval 95%)				
BGF MDI 320/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	-0.51 (-0.68 to -0.34)	-0.37 (-0.54 to -0.20)
BGF MDI 160/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	-0.35 (-0.53 to -0.18)	-0.22 (-0.39 to -0.05)

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of subjects achieving a MCID of 4 units or more in SGRQ total score

End point title	Percentage of subjects achieving a MCID of 4 units or more in SGRQ total score
End point description: Percentage of subjects achieving a minimal clinically important difference (MCID) of 4 units or more in SGRQ (St. George's Respiratory Questionnaire) total score at Week 24	
End point type	Secondary
End point timeframe: at Week 24	

End point values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg	BFF MDI 320/9.6 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2137	2121	2120	2131
Units: Odds Ratio				
number (confidence interval 95%)				
BGF MDI 320/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	1.358 (1.199 to 1.539)	1.246 (1.100 to 1.410)
BGF MDI 160/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	1.283 (1.133 to 1.454)	1.177 (1.039 to 1.333)

## Statistical analyses

No statistical analyses for this end point

**Secondary: Time to death (all cause)**

End point title	Time to death (all cause)
End point description:	
Time to death (all cause)	
End point type	Secondary
End point timeframe:	
52 Weeks	

End point values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg	BFF MDI 320/9.6 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2137	2121	2120	2131
Units: Hazard ratio				
number (confidence interval 95%)				
BGF MDI 320/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.544 (0.340 to 0.870)	0.782 (0.472 to 1.296)
BGF MDI 160/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.789 (0.518 to 1.201)	1.134 (0.716 to 1.796)

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Rate of severe COPD exacerbations**

End point title	Rate of severe COPD exacerbations
End point description:	
Rate of severe COPD exacerbations	
End point type	Secondary
End point timeframe:	
52 Weeks	

End point values	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg	BFF MDI 320/9.6 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2137	2121	2120	2131
Units: adjusted rate ratio (comparison)				
number (confidence interval 95%)				
BGF MDI 320/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.84 (0.69 to 1.03)	0.80 (0.66 to 0.97)
BGF MDI 160/14.4/9.6 µg	999999999 (999999999 to 999999999)	999999999 (999999999 to 999999999)	0.88 (0.72 to 1.08)	0.83 (0.69 to 1.01)

## **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Serious Adverse events were collected from the time subject signed Informed Consent to the time of the final follow-up telephone call. Adverse Events were collected from the time subject was randomized

Adverse event reporting additional description:

The Safety Population was defined as all subjects who were randomized to treatment and received at least 1 dose of the study drug

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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### Reporting groups

Reporting group title	BGF MDI 320/14.4/9.6 µg
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Reporting group description:

Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation 320/14.4/9.6 µg

Reporting group title	BGF MDI 160/14.4/9.6 µg
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Reporting group description:

Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation 160/14.4/9.6 µg

Reporting group title	GFF MDI 14.4/9.6 µg
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Reporting group description:

Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation 14.4/9.6 µg

Reporting group title	BFF MDI 320/9.6 µg
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Reporting group description:

Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhalation 320/9.6 µg

Serious adverse events	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	426 / 2144 (19.87%)	445 / 2124 (20.95%)	433 / 2125 (20.38%)
number of deaths (all causes)	27	42	47
number of deaths resulting from adverse events	20	28	35
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung neoplasm malignant			
subjects affected / exposed	4 / 2144 (0.19%)	5 / 2124 (0.24%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Prostate cancer			
subjects affected / exposed	3 / 2144 (0.14%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lung adenocarcinoma			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	0 / 2125 (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
Transitional cell carcinoma			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	0 / 2125 (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
Metastases to liver			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	0 / 2125 (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
Pancreatic carcinoma metastatic			



subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Small cell lung cancer			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Bronchial carcinoma			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 palate neoplasm			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	0 / 2125 (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
Metastases to central nervous system			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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 wall neoplasm			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenosquamous cell lung cancer			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Breast cancer in situ			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage IV			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Gastric cancer			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 lymphoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal cancer			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
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 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Hepatocellular carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 breast carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 squamous cell carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to nervous system			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 cancer metastatic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 adenocarcinoma			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Recosigmoid cancer			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsil cancer			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Non-Hodgkins lymphoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	3 / 2144 (0.14%)	3 / 2124 (0.14%)	0 / 2125 (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
Deep vein thrombosis			
subjects affected / exposed	4 / 2144 (0.19%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	0 / 2125 (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
Aortic aneurysm			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Arteriosclerosis			

subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery occlusion			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Peripheral Ischaemia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Peripheral vascular disorder			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accelerated hypertension			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic arteriosclerosis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 stenosis			



subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Peripheral artery occlusion			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Shock Haemorrhagic			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Subclavian artery stenosis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Thrombophlebitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 2144 (0.05%)	4 / 2124 (0.19%)	7 / 2125 (0.33%)
occurrences causally related to treatment / all	0 / 1	0 / 4	1 / 7
deaths causally related to treatment / all	1 / 1	4 / 4	7 / 7
Chest pain			

subjects affected / exposed	3 / 2144 (0.14%)	4 / 2124 (0.19%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Sudden death			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Oedema peripheral			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capsular contracture associated with breast implant			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (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
Pain			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue inflammation			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Sudden cardiac death			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	4 / 2144 (0.19%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Allergy to arthropod sting			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type I hypersensitivity			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Endometrial hyperplasia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Ovarian Cyst			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal cyst			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal leukoplakia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	202 / 2144 (9.42%)	221 / 2124 (10.40%)	219 / 2125 (10.31%)
occurrences causally related to treatment / all	16 / 255	21 / 263	12 / 268
deaths causally related to treatment / all	3 / 3	3 / 3	2 / 2
Acute respiratory failure			

subjects affected / exposed	14 / 2144 (0.65%)	20 / 2124 (0.94%)	20 / 2125 (0.94%)
occurrences causally related to treatment / all	0 / 16	0 / 20	1 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	10 / 2144 (0.47%)	9 / 2124 (0.42%)	5 / 2125 (0.24%)
occurrences causally related to treatment / all	0 / 10	0 / 9	0 / 5
deaths causally related to treatment / all	2 / 2	2 / 2	0 / 0
Pulmonary embolism			
subjects affected / exposed	4 / 2144 (0.19%)	3 / 2124 (0.14%)	5 / 2125 (0.24%)
occurrences causally related to treatment / all	1 / 4	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 2144 (0.00%)	3 / 2124 (0.14%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 2144 (0.00%)	3 / 2124 (0.14%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	3 / 2144 (0.14%)	0 / 2124 (0.00%)	0 / 2125 (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
Acute pulmonary oedema			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	0 / 2125 (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
Pleural effusion			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Pleurisy			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal polyp			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	0 / 2125 (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
Organising pneumonia			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 arrest			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord leukoplakia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Bronchial secretion retention			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Bronchospasm			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystic lung disease			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Haemothorax			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal congestion			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Nasal turbinate hypertrophy			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 calcification			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 aspiration			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	0 / 2125 (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
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective disorder			



subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Suicide attempt			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Affective disorder			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Persistent depressive disorder			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Troponin increased			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Blood folate decreased			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 magnesium decreased			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Electrocradiogram ST-T change			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Electrocardiogram abnormal			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Prothrombin time abnormal			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	4 / 2144 (0.19%)	3 / 2124 (0.14%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	3 / 2144 (0.14%)	0 / 2124 (0.00%)	0 / 2125 (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
Fall			

subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	0 / 2125 (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
Femur fracture			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Spinal compression fracture			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wound dehiscence			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Lumbar vertebral fracture			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Post procedural hemorrhage			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Concussion			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epicondylitis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Foreign body aspiration			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand Fracture			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humeral fracture			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 dislocation			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Ocular procedural complication			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 pneumothorax			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Radiation proctitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 hematoma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venomous bite			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 decomposition			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			

subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating abdominal trauma			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoconiosis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
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	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 evisceration			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			



subjects affected / exposed	7 / 2144 (0.33%)	10 / 2124 (0.47%)	17 / 2125 (0.80%)
occurrences causally related to treatment / all	0 / 8	0 / 10	2 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Atrial fibrillation			
subjects affected / exposed	9 / 2144 (0.42%)	8 / 2124 (0.38%)	14 / 2125 (0.66%)
occurrences causally related to treatment / all	0 / 9	3 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	5 / 2144 (0.23%)	5 / 2124 (0.24%)	7 / 2125 (0.33%)
occurrences causally related to treatment / all	0 / 5	1 / 5	0 / 7
deaths causally related to treatment / all	1 / 1	1 / 1	3 / 3
Coronary artery disease			
subjects affected / exposed	5 / 2144 (0.23%)	5 / 2124 (0.24%)	7 / 2125 (0.33%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	5 / 2144 (0.23%)	3 / 2124 (0.14%)	5 / 2125 (0.24%)
occurrences causally related to treatment / all	0 / 6	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	3 / 2144 (0.14%)	1 / 2124 (0.05%)	8 / 2125 (0.38%)
occurrences causally related to treatment / all	1 / 3	0 / 1	1 / 8
deaths causally related to treatment / all	3 / 3	0 / 0	7 / 7
Angina pectoris			
subjects affected / exposed	3 / 2144 (0.14%)	0 / 2124 (0.00%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 2144 (0.05%)	3 / 2124 (0.14%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			

subjects affected / exposed	3 / 2144 (0.14%)	1 / 2124 (0.05%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Cardiorespiratory arrest			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	1 / 1	3 / 3
Acute coronary syndrome			
subjects affected / exposed	1 / 2144 (0.05%)	3 / 2124 (0.14%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 2144 (0.00%)	3 / 2124 (0.14%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Supraventricular tachycardia			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			

subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 ischaemia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorder			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Cardio-respiratory distress			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 chronic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 cardiomyopathy			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Left ventricular failure			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Mitral valve incompetence			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Tachycardia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trifascicular block			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Cor pulmonale			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	8 / 2144 (0.37%)	2 / 2124 (0.09%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 4
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Syncope			
subjects affected / exposed	2 / 2144 (0.09%)	3 / 2124 (0.14%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Carotid artery stenosis			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	0 / 2125 (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
Siezure			

subjects affected / exposed	1 / 2144 (0.05%)	4 / 2124 (0.19%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Cerebellar infarction			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	0 / 2125 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Cervical radiculopathy			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Colloid brain cyst			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic Cerebral infarction			



subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 intercranial			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemorrhagic stroke			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyopercapnic coma			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Monoparesis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal claudication			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	3 / 2144 (0.14%)	0 / 2124 (0.00%)	0 / 2125 (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
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Anaemia			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	0 / 2125 (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
Iron deficiency anaemia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 macrocytic			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Lymphadenopathy			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Neutropenia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Vertigo			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Retinal detachment			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Eyelid ptosis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vascular thrombosis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Retinal degeneration			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Small intestine obstruction			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdonimal pain			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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 hernia			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Large intestine polyp			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis microscopic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoroidal haemorrhage			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids thrombosed			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 Infarction			



subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 obstruction			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal polyp			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive pancreatitis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toothache			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Varices oesophageal			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Cholecystitis acute			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	3 / 2144 (0.14%)	0 / 2124 (0.00%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct obstruction			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Cholecystitis Chronic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 function abnormal			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (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
Hepatitis toxic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Skin lesion			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Swelling face			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Urticaria			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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	2 / 2144 (0.09%)	1 / 2124 (0.05%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Acute kidney injury			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	0 / 2125 (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
Urinary retention			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Anuria			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Chronic kidney disease			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Haemorrhage urinary tract			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Hydronephrosis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 urinary tract symptoms			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 bladder haemorrhage			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Glomerulonephritis chronic			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Adrenal mass			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Musculoskeletal and connective tissue disorders</b>			
Osteoarthritis			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 2144 (0.09%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Arthralgia			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Intervertebral disc degeneration			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal ligament			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Synovitis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
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 spinal stenosis			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	0 / 2125 (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
Musculoskeletal pain			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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			
Pneumonia			
subjects affected / exposed	61 / 2144 (2.85%)	59 / 2124 (2.78%)	35 / 2125 (1.65%)
occurrences causally related to treatment / all	8 / 63	3 / 64	3 / 37
deaths causally related to treatment / all	1 / 1	1 / 1	2 / 2
Sepsis			



subjects affected / exposed	7 / 2144 (0.33%)	5 / 2124 (0.24%)	5 / 2125 (0.24%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	4 / 2144 (0.19%)	6 / 2124 (0.28%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	4 / 2144 (0.19%)	2 / 2124 (0.09%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	3 / 2144 (0.14%)	3 / 2124 (0.14%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	2 / 2144 (0.09%)	3 / 2124 (0.14%)	4 / 2125 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 2144 (0.05%)	4 / 2124 (0.19%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	2 / 2144 (0.09%)	2 / 2124 (0.09%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 2144 (0.05%)	2 / 2124 (0.09%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	3 / 2144 (0.14%)	0 / 2124 (0.00%)	0 / 2125 (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
Pneumonia viral			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	0 / 2125 (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
Staphylococcal infection			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	3 / 2125 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	2 / 2125 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Gastroenteritis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	1 / 2124 (0.05%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Bacterial pyelonephritis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis allergic			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Bursitis infective			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 cellulitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 infective			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Emphysematous cholecystitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis brain stem			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Epididymitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 salmonella			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 shigella			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Histoplasmosis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Infected bite			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected dermal cyst			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			

subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Localised infection			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micrococcus infection			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otosalpingitis			

subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perichondritis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pseudomonal			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Post procedural sepsis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			



subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Viral infection			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
Metapneumovirus infection			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 streptococcal			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Fluid overload			
subjects affected / exposed	0 / 2144 (0.00%)	2 / 2124 (0.09%)	0 / 2125 (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
Hyperglycaemia			
subjects affected / exposed	2 / 2144 (0.09%)	0 / 2124 (0.00%)	0 / 2125 (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
Hypoglycaemia			

subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Hyponatremia			
subjects affected / exposed	1 / 2144 (0.05%)	1 / 2124 (0.05%)	0 / 2125 (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
Abnormal loss of weight			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
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 melitus			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	1 / 2125 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes melitus inadequate control			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperlipidemia			
subjects affected / exposed	1 / 2144 (0.05%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired fasting glucose			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
<b>Obesity</b>			
subjects affected / exposed	0 / 2144 (0.00%)	1 / 2124 (0.05%)	0 / 2125 (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
<b>Vitamin B12 deficiency</b>			
subjects affected / exposed	0 / 2144 (0.00%)	0 / 2124 (0.00%)	0 / 2125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	BFF MDI 320/9.6 µg		
<b>Total subjects affected by serious adverse events</b>			
subjects affected / exposed	440 / 2136 (20.60%)		
number of deaths (all causes)	35		
number of deaths resulting from adverse events	29		
<b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b>			
<b>Lung neoplasm malignant</b>			
subjects affected / exposed	4 / 2136 (0.19%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	1 / 1		
<b>Prostate cancer</b>			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
<b>Lung adenocarcinoma</b>			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
<b>Non-small cell lung cancer</b>			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Transitional cell carcinoma subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to liver subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal carcinoma subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Breast cancer subjects affected / exposed	2 / 2136 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma metastatic subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	1 / 1			
Small cell lung cancer subjects affected / exposed	2 / 2136 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma				

subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal cell carcinoma				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign lung neoplasm				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colorectal cancer				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant palate neoplasm				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to lung				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma				

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall neoplasm			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma gastric			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenosquamous cell lung cancer			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer in situ			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer stage IV			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer metastatic			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon neoplasm			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal lymphoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal cancer			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cancer metastatic			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatocellular carcinoma			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Invasive breast carcinoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			



subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to nervous system				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic bronchial carcinoma				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal cancer metastatic				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal squamous cell carcinoma				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Papillary renal cell carcinoma				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal adenocarcinoma				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectosigmoid cancer				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cancer				

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal neoplasm			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsil cancer			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-Hodgkins lymphoma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung neoplasm			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			

subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive urgency			

subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Iliac artery occlusion				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral Ischaemia				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral vascular disorder				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Accelerated hypertension				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic arteriosclerosis				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic stenosis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery occlusion				

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral artery stenosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock Haemorrhagic			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subclavian artery stenosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	2 / 2		
Chest pain			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	1 / 1		
Sudden death			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	1 / 1		
Drug withdrawal syndrome			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Capsular contracture associated with breast implant			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Soft tissue inflammation			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden cardiac death			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	4 / 2136 (0.19%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Allergy to arthropod sting			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type I hypersensitivity			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Endometrial hyperplasia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian Cyst			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Scrotal cyst			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal leukoplakia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	241 / 2136 (11.28%)		
occurrences causally related to treatment / all	17 / 299		
deaths causally related to treatment / all	4 / 4		
Acute respiratory failure			
subjects affected / exposed	7 / 2136 (0.33%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	9 / 2136 (0.42%)		
occurrences causally related to treatment / all	1 / 9		
deaths causally related to treatment / all	3 / 3		
Pulmonary embolism			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		



Pneumothorax				
subjects affected / exposed	4 / 2136 (0.19%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	2 / 2136 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary mass				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute pulmonary oedema				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic respiratory failure				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleurisy				

subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory distress			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laryngeal polyp			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory arrest			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vocal cord leukoplakia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial secretion retention			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystic lung disease			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemothorax			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercapnia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal congestion			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal polyps			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleuritic pain			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary calcification			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary fibrosis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schizoaffective disorder			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Affective disorder			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcoholism			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hallucination			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Persistent depressive disorder			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Troponin increased			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood folate decreased			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood magnesium decreased			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrocardiogram ST-T change			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrocardiogram abnormal			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oxygen saturation decreased			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prothrombin time abnormal			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Hip fracture			
subjects affected / exposed	5 / 2136 (0.23%)		
occurrences causally related to treatment / all	1 / 5		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wound dehiscence			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foot fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural hemorrhage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epicondylitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body aspiration			



subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body in gastrointestinal tract			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hand Fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Humerous fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaw fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb traumatic amputation			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ocular procedural complication			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural pneumothorax			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pubis fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation proctitis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sternal fracture			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural hematoma			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venomous bite			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound decomposition			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penetrating abdominal trauma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumoconiosis			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal fracture			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound evisceration			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	7 / 2136 (0.33%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	4 / 2136 (0.19%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	1 / 1		
Coronary artery disease			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	5 / 2136 (0.23%)		
occurrences causally related to treatment / all	1 / 5		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiorespiratory arrest			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	2 / 2		
Acute coronary syndrome			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis coronary artery			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute left ventricular failure			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulseless electrical activity			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block second degree			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorder			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory distress			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiogenic shock			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiovascular disorder			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiovascular insufficiency			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive heart disease			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			



subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocarditis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Trifascicular block			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cor pulmonale			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Right ventricular failure			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	4 / 2136 (0.19%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	5 / 2136 (0.23%)		
occurrences causally related to treatment / all	1 / 5		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
S seizure			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebellar infarction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial aneurysm			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain injury			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical radiculopathy			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colloid brain cyst			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolic Cerebral infarction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemorrhagic stroke			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyopercapnic coma			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intercostal neuralgia			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lacunar infarction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Monoparesis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelopathy			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ruptured cerebral aneurysm			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal claudication			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord paralysis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Blood and lymphatic system disorders</b>			
<b>Anaemia</b>			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Iron deficiency anaemia</b>			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Anaemia macrocytic</b>			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Immune thrombocytopenic purpura</b>			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Lymphadenopathy</b>			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Neutropenia</b>			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Thrombocytopenia</b>			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Ear and labyrinth disorders</b>			

Vertigo			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid ptosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal vascular thrombosis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Visual impairment			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal degeneration			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	1 / 1		



Small intestine obstruction				
subjects affected / exposed	2 / 2136 (0.09%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abdonimal pain				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal hernia				

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis ulcerative			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticular perforation			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcennr			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis microscopic			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal perforation			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysphagia			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer perforation			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoroidal haemorrhage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impaired gastric emptying			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal Infarction			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal polyp			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesenteric artery stenosis			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Obstructive pancreatitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toothache			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varices oesophageal			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erosive oesophagitis			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestinal haemorrhage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bile duct obstruction			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis Chronic			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic function abnormal			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis toxic			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Skin lesion			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			

subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anuria			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage urinary tract			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower urinary tract symptoms			



subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis chronic			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenal mass			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteorthritis			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Intervertebral disc protrusion				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Costochondritis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin pain				

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc degeneration			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rhabdomyolysis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal ligament			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical spinal stenosis			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	55 / 2136 (2.57%)		
occurrences causally related to treatment / all	4 / 57		
deaths causally related to treatment / all	1 / 1		
Sepsis			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	2 / 2		
Cellulitis			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	7 / 2136 (0.33%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			

subjects affected / exposed	4 / 2136 (0.19%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	3 / 2136 (0.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	1 / 1		
Erysipelas			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	2 / 2136 (0.09%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonitis			

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia pneumococcal			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial pyelonephritis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			

subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchopulmonary aspergillosis allergic				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis infective				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter infection				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Catheter site cellulitis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis of male external genital organ				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic abscess				



subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Emphysematous cholecystitis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis brain stem			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epididymitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis norovirus			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis shigella			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			

subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
H1N1 influenza				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Histoplasmosis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected bite				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected dermal cyst				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of bronchiectasis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastitis				

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Micrococcus infection			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal candidiasis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otosalpingitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perichondritis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia pseudomonal			

subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural sepsis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
subjects affected / exposed	1 / 2136 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vaginal infection				
subjects affected / exposed	0 / 2136 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				

subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus infection			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Fluid overload			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatremia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abnormal loss of weight			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dehydration			

subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes melitus			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes melitus inadequate control			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperlipidemia			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impaired fasting glucose			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	0 / 2136 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitamin B12 deficiency			
subjects affected / exposed	1 / 2136 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	BGF MDI 320/14.4/9.6 µg	BGF MDI 160/14.4/9.6 µg	GFF MDI 14.4/9.6 µg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	337 / 2144 (15.72%)	361 / 2124 (17.00%)	292 / 2125 (13.74%)
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	227 / 2144 (10.59%)	239 / 2124 (11.25%)	199 / 2125 (9.36%)
occurrences (all)	290	315	255
Upper respiratory tract infection			
subjects affected / exposed	123 / 2144 (5.74%)	137 / 2124 (6.45%)	102 / 2125 (4.80%)
occurrences (all)	149	176	129

<b>Non-serious adverse events</b>	BFF MDI 320/9.6 µg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	336 / 2136 (15.73%)		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	234 / 2136 (10.96%)		
occurrences (all)	331		
Upper respiratory tract infection			
subjects affected / exposed	115 / 2136 (5.38%)		
occurrences (all)	154		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 July 2015	Updated Study Design, Investigational Plan, Design figure, Rationale of Study Design , Inclusion/exclusion criteria
17 August 2015	Synopsis: Study Design: Paragraph, overall Design and Plan updated Secondary Efficacy Endpoints, Other Efficacy Endpoints, 24-Hour Holter Monitoring Sub-study Endpoints, Interim Efficacy Analysis, List of Abbreviations and Definitions of Terms, inclusion exclusion criteria updated
08 January 2016	Synopsis: Study Design: Paragraph, overall Design and Plan updated Secondary Efficacy Endpoints, Other Efficacy Endpoints, 24-Hour Holter Monitoring Sub-study Endpoints, Interim Efficacy Analysis, List of Abbreviations and Definitions of Terms, inclusion exclusion criteria updated
25 August 2016	Changed Sponsor Contact on title and sponsor signature page Revised Secondary Efficacy Endpoints and Other Endpoints Revised Synopsis, all descriptions of covariates in efficacy analyses "or caffeine-containing medications" as these, in addition to caffeine-containing foods and beverages, are not allowed within 6 hours of and during an in-clinic visit since they may affect lung function measurements. Revised exclusion criteria Prohibited meds revised updated treatment discontinuation
19 September 2016	Added additional section references for Treatment discontinuation Duration of study updated from "not expected to exceed 40 months" to "not expected to exceed 50 months" Removed other efficacy endpoints, other 24hour Holter monitoring sub-study endpoints, and healthcare resource utilization endpoints Exclusion Criterion updated Added description of medication allowed during the treatment of severe COPD exacerbations Renamed adjudication committees to the Clinical Endpoint Committee to reflect current process and terminology
03 November 2017	Added additional section references for Treatment discontinuation Duration of study updated from "not expected to exceed 40 months" to "not expected to exceed 50 months" Removed other efficacy endpoints, other 24hour Holter monitoring sub-study endpoints, and healthcare resource utilization endpoints Exclusion Criterion updated Added description of medication allowed during the treatment of severe COPD exacerbations Renamed adjudication committees to the Clinical Endpoint Committee to reflect current process and terminology
27 March 2018	Added secondary objective 24-hour Holter monitoring sub-study endpoints added Updated the definition for the duration of moderate or severe COPD exacerbations The non-inferiority (NI) margin was update Criteria for upper limit for Glucose were changed for potentially clinically significant laboratory values



21 June 2019	Added secondary objective 24-hour Holter monitoring sub-study endpoints added Updated the definition for the duration of moderate or severe COPD exacerbations The non-inferiority (NI) margin was update Criteria for upper limit for Glucose were changed for potentially clinically significant laboratory values
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Notes:

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## **Interruptions (globally)**

Were there any global interruptions to the trial? No

## **Limitations and caveats**

None reported