



## Clinical trial results:

### A Clinical Outcomes Study to compare the effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardiovascular disease.

#### Summary

EudraCT number	2010-021638-72
Trial protocol	CZ SK LV AT DE GB DK PL GR BG ES IT NL BE
Global end of trial date	15 July 2015

#### Results information

Result version number	v1 (current)
This version publication date	31 March 2016
First version publication date	31 March 2016

#### Trial information

##### Trial identification

Sponsor protocol code	HZC113782
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01313676
WHO universal trial number (UTN)	-
Other trial identifiers	N/A: N/A

Notes:

#### Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	Clinical Trails Helpdesk, GlaxoSmithKline Research & Development Ltd, +44 0208990 44 66, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trails Helpdesk, GlaxoSmithKline Research & Development Ltd, +44 0208990 44 66, GSKClinicalSupportHD@gsk.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	07 September 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 July 2015
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to prospectively evaluate the effect of Fluticasone Furoate (FF)/Vilanterol (VI) inhalation powder 100/25mcg QD compared with placebo on survival in subjects with moderate COPD ( $\geq 50$  and  $\leq 70$  % predicted FEV1) and a history of, or at increased risk for developing, cardiovascular disease.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 January 2011
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: 711
Country: Number of subjects enrolled	Australia: 77
Country: Number of subjects enrolled	Austria: 149
Country: Number of subjects enrolled	Hungary: 352
Country: Number of subjects enrolled	India: 476
Country: Number of subjects enrolled	Indonesia: 203
Country: Number of subjects enrolled	Israel: 85
Country: Number of subjects enrolled	Belarus: 26
Country: Number of subjects enrolled	Belgium: 12
Country: Number of subjects enrolled	Bosnia and Herzegovina: 453
Country: Number of subjects enrolled	Bulgaria: 717
Country: Number of subjects enrolled	Canada: 125
Country: Number of subjects enrolled	Chile: 93
Country: Number of subjects enrolled	China: 742
Country: Number of subjects enrolled	Colombia: 175
Country: Number of subjects enrolled	Croatia: 350
Country: Number of subjects enrolled	Czech Republic: 602
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	Georgia: 620
Country: Number of subjects enrolled	Germany: 840

Country: Number of subjects enrolled	Greece: 57
Country: Number of subjects enrolled	Japan: 239
Country: Number of subjects enrolled	Korea, Republic of: 275
Country: Number of subjects enrolled	Latvia: 449
Country: Number of subjects enrolled	Macedonia, the former Yugoslav Republic of: 766
Country: Number of subjects enrolled	Malaysia: 42
Country: Number of subjects enrolled	Mexico: 156
Country: Number of subjects enrolled	Netherlands: 16
Country: Number of subjects enrolled	Philippines: 1262
Country: Number of subjects enrolled	Poland: 1850
Country: Number of subjects enrolled	Romania: 712
Country: Number of subjects enrolled	Russian Federation: 1578
Country: Number of subjects enrolled	Serbia: 246
Country: Number of subjects enrolled	Slovakia: 151
Country: Number of subjects enrolled	South Africa: 647
Country: Number of subjects enrolled	Spain: 195
Country: Number of subjects enrolled	Taiwan: 79
Country: Number of subjects enrolled	Thailand: 162
Country: Number of subjects enrolled	Turkey: 43
Country: Number of subjects enrolled	Ukraine: 1482
Country: Number of subjects enrolled	United Kingdom: 245
Country: Number of subjects enrolled	United States: 6132
Country: Number of subjects enrolled	Vietnam: 231
Worldwide total number of subjects	23835
EEA total number of subjects	6709

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	10578
From 65 to 84 years	13257
85 years and over	0

## Subject disposition

### Recruitment

#### Recruitment details:

This study was conducted at 1373 sites. The study employed an event-driven design and was to conclude when approximately 1000 reports of a primary outcome event of death were received. The study consisted of a 4-10 day run-in period, variable treatment period until the required number of events was achieved, and 1 week follow-up period.

### Pre-assignment

#### Screening details:

A total of 23,835 participants were screened, of whom 16,590 were randomized. Of the 16,590 participants randomized, 16,568 participants received a single dose of investigational product (IP) and were assigned to a treatment and included in the Safety Population.

### 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, Data analyst, Carer, Assessor

### Arms

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

#### Arm description:

Participants received placebo once daily (OD) in the morning from the dry powder inhaler (DPI) until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Arm type	Placebo Comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

#### Dosage and administration details:

The formulation is available in two strips. First strip contains lactose and second strip contains blend of lactose and magnesium stearate. The formulation was an inhaler (ELLIPTA) which contained 30 doses. It was administered once daily via dry powder inhaler in morning.

<b>Arm title</b>	Fluticasone furoate 100 µg
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#### Arm description:

Participants received Fluticasone Furoate (FF) 100 microgram (µg) inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Fluticasone furoate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

#### Dosage and administration details:

Formulation is available in two strips and contains 100µg fluticasone furoate per blister. First strip contains fluticasone furoate blended with lactose and second strip contains blend of lactose and magnesium stearate. The formulation was an inhaler (ELLIPTA) which contained 30 doses. It was administered as 100µg dose once daily via dry powder inhaler in morning.

<b>Arm title</b>	Vilanterol 25 µg
Arm description: Participants received Vilanterol (VI) 25 µg inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.	
Arm type	Experimental
Investigational medicinal product name	Vilanterol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

**Dosage and administration details:**

Formulation is available in two strips and contains 25µg vilanterol per blister. First strip contains vilanterol blended with lactose and magnesium stearate and second strip contains lactose. The formulation was an inhaler (ELLIPTA) which contained 30 doses. It was administered as 25µg dose once daily via dry powder inhaler in morning.

<b>Arm title</b>	Fluticasone furoate/vilanterol 100/25 µg
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**Arm description:**

Participants received FF/VI 100/25 µg inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Arm type	Experimental
Investigational medicinal product name	Fluticasone furoate/vilanterol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

**Dosage and administration details:**

Formulation is available in two strips and contains 100µg fluticasone furoate/25µg vilanterol per blister. First strip contains fluticasone furoate blended with lactose and second strip contains vilanterol blended with lactose and magnesium stearate. The formulation was an inhaler (ELLIPTA) which contained 30 doses. It was administered as 100µg/25µg dose once daily via dry powder inhaler in morning.

<b>Number of subjects in period 1<sup>[1]</sup></b>	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg
Started	4131	4157	4140
Completed	2881	3044	3052
Not completed	1250	1113	1088
Physician decision	53	64	62
Adverse Event	395	365	372
Decision by Participant or Proxy	643	527	515
Met Protocol-Defined Stopping Criteria	3	4	2
Study Closed/terminated	7	6	9
Sponsor Terminated Study Treatment	1	1	-
Investigator Site Closed	12	11	15
Lost to follow-up	-	-	1
Missing	1	1	1

Lack of efficacy	98	90	65
Protocol deviation	37	44	46

<b>Number of subjects in period 1<sup>[1]</sup></b>	Fluticasone furoate/vilanterol 100/25 µg
Started	4140
Completed	3146
Not completed	994
Physician decision	48
Adverse Event	333
Decision by Participant or Proxy	492
Met Protocol-Defined Stopping Criteria	11
Study Closed/terminated	9
Sponsor Terminated Study Treatment	1
Investigator Site Closed	10
Lost to follow-up	-
Missing	-
Lack of efficacy	46
Protocol deviation	44

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total of 23,835 participants were screened, of whom 16,590 were randomized. Of the 16,590 participants randomized, 16,568 participants received a single dose of investigational product (IP) and were assigned to a treatment and included in the Safety Population.

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants received placebo once daily (OD) in the morning from the dry powder inhaler (DPI) until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Reporting group title	Fluticasone furoate 100 µg
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Reporting group description:

Participants received Fluticasone Furoate (FF) 100 microgram (µg) inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Reporting group title	Vilanterol 25 µg
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Reporting group description:

Participants received Vilanterol (VI) 25 µg inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Reporting group title	Fluticasone furoate/vilanterol 100/25 µg
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Reporting group description:

Participants received FF/VI 100/25 µg inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.

Reporting group values	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg
Number of subjects	4131	4157	4140
Age categorical Units: Subjects			

Age continuous Units: years			
geometric mean	65.2	65	65.2
standard deviation	± 7.9	± 8.02	± 7.68
Gender categorical Units: Subjects			
Female	1050	1098	1071
Male	3081	3059	3069
Race, Customized Units: Subjects			
African American /African Heritage	61	62	68
American Indian or Alaskan Native	9	5	4
Asian - Central /South Asian Heritage	64	55	62
Asian - East Asian Heritage	192	193	195
Asian - Japanese Heritage	34	36	37
Asian - Mixed Race	1	0	0
Asian - South East Asian Heritage	389	399	386
Native Hawaiian or Other Pacific Islander	1	2	0
White - Arabic/North African Heritage	14	13	7
White - Mixed Race	0	0	0

White - White/Caucasian /European Heritage	3334	3367	3353
Mixed Race	32	25	28

<b>Reporting group values</b>	Fluticasone furoate/vilanterol 100/25 µg	Total	
Number of subjects	4140	16568	
Age categorical Units: Subjects			

Age continuous Units: years geometric mean standard deviation	65.3 ± 7.97	-	
Gender categorical Units: Subjects			
Female	1019	4238	
Male	3121	12330	
Race, Customized Units: Subjects			
African American /African Heritage	69	260	
American Indian or Alaskan Native	9	27	
Asian - Central /South Asian Heritage	57	238	
Asian - East Asian Heritage	192	772	
Asian - Japanese Heritage	37	144	
Asian - Mixed Race	0	1	
Asian - South East Asian Heritage	394	1568	
Native Hawaiian or Other Pacific Islander	2	5	
White - Arabic/North African Heritage	12	46	
White - Mixed Race	1	1	
White - White/Caucasian /European Heritage	3337	13391	
Mixed Race	30	115	



## End points

### End points reporting groups

Reporting group title	Placebo
Reporting group description: Participants received placebo once daily (OD) in the morning from the dry powder inhaler (DPI) until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.	
Reporting group title	Fluticasone furoate 100 µg
Reporting group description: Participants received Fluticasone Furoate (FF) 100 microgram (µg) inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.	
Reporting group title	Vilanterol 25 µg
Reporting group description: Participants received Vilanterol (VI) 25 µg inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.	
Reporting group title	Fluticasone furoate/vilanterol 100/25 µg
Reporting group description: Participants received FF/VI 100/25 µg inhalation powder OD in the morning from the DPI until the required number of events (death) was achieved. Participants were provided albuterol/salbutamol inhalation aerosol to be used as rescue medication during the Treatment Period.	

### Primary: Number of participants with death (both on and off treatment) due to any cause, time up to or on the pre-determined common end date

End point title	Number of participants with death (both on and off treatment) due to any cause, time up to or on the pre-determined common end date
End point description: Death from any cause: which occurred from the day of starting IP until the Commone End Date (CED). Common End Date (CED) is the study end date that was pre determined where approximately 1000 deaths would have occurred in the Intent-toTreat Efficacy (ITT-E) Population. Only deaths which occurred on or before the CED were used for the primary analysis. Those who had not died by CED, but who were known to be alive on or after the CED, were censored at the CED. Cox Proportional Hazards (PH) Model was adjusted for age, and gender, including all 4 arms. A hazard ratio of less than 1 indicates a lower death rate versus placebo or other arm. ITT-E Population consisted of all participants in the Safety Population (i.e. randomized to IP and who received at least one dose of IP), with the exception of those recruited at sites that were closed.	
End point type	Primary
End point timeframe: From the date of randomization until date of death due to any cause (average of 2 study years)	

End point values	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg	Fluticasone furoate/vilanterol 100/25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4111 <sup>[1]</sup>	4135 <sup>[2]</sup>	4118 <sup>[3]</sup>	4121 <sup>[4]</sup>
Units: Participants				
Dead	275	251	265	246
Alive	3832	3884	3853	3874

Unknown	4	0	0	1
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Notes:

[1] - ITT-E Population

[2] - ITT-E Population

[3] - ITT-E Population

[4] - ITT-E Population

## Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis 1
Comparison groups	Placebo v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8232
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.137
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.878
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.739
upper limit	1.042

<b>Statistical analysis title</b>	Statistical Analysis 2
Comparison groups	Placebo v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8232
Analysis specification	Pre-specified
Analysis type	superiority <sup>[5]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	12.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	26.1

Notes:

[5] - Confidence Interval (95%) and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as (1-hazard ratio)\*100

<b>Statistical analysis title</b>	Statistical Analysis 3
Comparison groups	Placebo v Fluticasone furoate 100 µg
Number of subjects included in analysis	8246
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.284
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.911

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.767
upper limit	1.081

<b>Statistical analysis title</b>	Statistical Analysis 4
Comparison groups	Placebo v Fluticasone furoate 100 µg
Number of subjects included in analysis	8246
Analysis specification	Pre-specified
Analysis type	superiority <sup>[6]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	8.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.1
upper limit	23.3

Notes:

[6] - Confidence Interval (95%) and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as (1-hazard ratio)\*100

<b>Statistical analysis title</b>	Statistical Analysis 5
Comparison groups	Placebo v Vilanterol 25 µg
Number of subjects included in analysis	8229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.655
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.962
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.813
upper limit	1.139

<b>Statistical analysis title</b>	Statistical Analysis 6
Comparison groups	Placebo v Vilanterol 25 µg
Number of subjects included in analysis	8229
Analysis specification	Pre-specified
Analysis type	superiority <sup>[7]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	3.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	18.7

Notes:

[7] - Confidence Interval (95%) and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as  $(1 - \text{hazard ratio}) \times 100$

<b>Statistical analysis title</b>	Statistical Analysis 7
Comparison groups	Fluticasone furoate 100 µg v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.681
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.964
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.808
upper limit	1.149

<b>Statistical analysis title</b>	Statistical Analysis 8
Comparison groups	Fluticasone furoate 100 µg v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8256
Analysis specification	Pre-specified
Analysis type	superiority <sup>[8]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.9
upper limit	19.2

Notes:

[8] - Confidence Interval (95%) and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as  $(1 - \text{hazard ratio}) \times 100$

<b>Statistical analysis title</b>	Statistical Analysis 9
Comparison groups	Vilanterol 25 µg v Fluticasone furoate/vilanterol 100/25 µg

Number of subjects included in analysis	8239
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.299
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.912
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.767
upper limit	1.085

<b>Statistical analysis title</b>	Statistical Analysis 10
Comparison groups	Vilanterol 25 µg v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8239
Analysis specification	Pre-specified
Analysis type	superiority <sup>[9]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	8.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.5
upper limit	23.3

Notes:

[9] - Confidence Interval (95%) and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as (1-hazard ratio)\*100

### **Secondary: Decline in forced expiratory volume in 1 second (FEV1)**

End point title	Decline in forced expiratory volume in 1 second (FEV1)
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End point description:

FEV1 is a measure of lung function and is defined as the maximal amount of air that can be forcefully exhaled in one second. The effect of treatment on decline of post bronchodilator FEV1 recorded during the treatment period was analyzed using a particular form of a mixed effect model - a random coefficients model. FEV1 was fitted as the response variable with treatment group, age, gender, baseline FEV1 and time on treatment as fixed effects. Time on treatment was treated as a continuous variable. This model allowed for an initial increase in FEV1, but then tested the difference in slopes from the first post-baseline measurement which was at 3 months. A negative slope indicates a decline. A positive treatment difference indicates a slower rate of decline vs Placebo or Component. Only participants with at least one on-treatment post-bronchodilator FEV1 measurement were analyzed.

End point type	Secondary
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End point timeframe:

From start date of IP until IP stop date + 1 (assessed up to 4 years)

<b>End point values</b>	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg	Fluticasone furoate/vilanterol 100/25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3800 <sup>[10]</sup>	3879 <sup>[11]</sup>	3866 <sup>[12]</sup>	3912 <sup>[13]</sup>
Units: milliliter/year				
least squares mean (standard error)	-46 (± 2.5)	-38 (± 2.4)	-47 (± 2.4)	-38 (± 2.4)

Notes:

[10] - ITT-E Population

[11] - ITT-E Population

[12] - ITT-E Population

[13] - ITT-E Population

## Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis 1
Comparison groups	Placebo v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	7712
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.019
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	15
Variability estimate	Standard error of the mean
Dispersion value	3.4

<b>Statistical analysis title</b>	Statistical Analysis 2
Comparison groups	Placebo v Fluticasone furoate 100 µg
Number of subjects included in analysis	7679
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.026
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1
upper limit	14
Variability estimate	Standard error of the mean
Dispersion value	3.5

<b>Statistical analysis title</b>	Statistical Analysis 3
Comparison groups	Placebo v Vilanterol 25 µg
Number of subjects included in analysis	7666
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.654
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	5
Variability estimate	Standard error of the mean
Dispersion value	3.4

<b>Statistical analysis title</b>	Statistical Analysis 4
Comparison groups	Fluticasone furoate 100 µg v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	7791
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.913
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	7
Variability estimate	Standard error of the mean
Dispersion value	3.4

<b>Statistical analysis title</b>	Statistical Analysis 5
Comparison groups	Vilanterol 25 µg v Fluticasone furoate/vilanterol 100/25 µg

Number of subjects included in analysis	7778
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10
Confidence interval	
level	95 %
sides	2-sided
lower limit	3
upper limit	16
Variability estimate	Standard error of the mean
Dispersion value	3.4

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**Secondary: Number of participants with first on-treatment cardiovascular (CV) composite events occurred on or before common end date**

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End point title	Number of participants with first on-treatment cardiovascular (CV) composite events occurred on or before common end date
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End point description:

On-treatment CV composite event is comprised of the first event that is adjudicated as on-treatment CV death, myocardial infarction, stroke, unstable angina, or transient ischemic attack experienced by a participant. The events that occurred no more than 7 days after the participants last dose of IP are considered as on-treatment adverse events. Common end date is the study end date where approximately 1000 deaths would have occurred in the ITT-E Population. Cox PH Model was used to assess time to first on-treatment CV composite event. Cox PH Model was adjusted for age, gender and indicators of ischemic and vascular disease, including all four treatment arms. A hazard ratio less than 1 indicates a lower risk of a first CV event rate versus placebo or any arm.

End point type	Secondary
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End point timeframe:

From the start of IP to first on treatment CV event till 7 days after the last dose of IP (average of 2 study years)

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End point values	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg	Fluticasone furoate/vilanterol 100/25 µg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4111 <sup>[14]</sup>	4135 <sup>[15]</sup>	4118 <sup>[16]</sup>	4121 <sup>[17]</sup>
Units: Participants				
Had CV composite event	173	161	180	174
No CV composite event	3938	3974	3938	3947

Notes:

[14] - ITT-E Population

[15] - ITT-E Population

[16] - ITT-E Population

[17] - ITT-E Population

**Statistical analyses**



<b>Statistical analysis title</b>	Statistical Analysis 1
Comparison groups	Placebo v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8232
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.475
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.926
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.143

<b>Statistical analysis title</b>	Statistical Analysis 2
Comparison groups	Placebo v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8232
Analysis specification	Pre-specified
Analysis type	superiority <sup>[18]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.3
upper limit	25

Notes:

[18] - Confidence Interval and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as  $(1 - \text{hazard ratio}) \times 100$

<b>Statistical analysis title</b>	Statistical Analysis 3
Comparison groups	Placebo v Fluticasone furoate 100 µg
Number of subjects included in analysis	8246
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.317
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.896
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.723
upper limit	1.111

<b>Statistical analysis title</b>	Statistical Analysis 4
Comparison groups	Placebo v Fluticasone furoate 100 µg
Number of subjects included in analysis	8246
Analysis specification	Pre-specified
Analysis type	superiority <sup>[19]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	10.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	27.7

Notes:

[19] - Confidence Interval and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as (1-hazard ratio)\*100

<b>Statistical analysis title</b>	Statistical Analysis 5
Comparison groups	Placebo v Vilanterol 25 µg
Number of subjects included in analysis	8229
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.908
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.988
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.802
upper limit	1.217

<b>Statistical analysis title</b>	Statistical Analysis 6
Comparison groups	Placebo v Vilanterol 25 µg
Number of subjects included in analysis	8229
Analysis specification	Pre-specified
Analysis type	superiority <sup>[20]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.7
upper limit	19.8

Notes:

[20] - Confidence Interval and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as (1-hazard ratio)\*100

<b>Statistical analysis title</b>	Statistical Analysis 7
Comparison groups	Fluticasone furoate 100 µg v Fluticasone furoate/vilanterol 100/25 µg

Number of subjects included in analysis	8256
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.763
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.033
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.834
upper limit	1.281

<b>Statistical analysis title</b>	Statistical Analysis 8
Comparison groups	Fluticasone furoate 100 µg v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8256
Analysis specification	Pre-specified
Analysis type	superiority <sup>[21]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.1
upper limit	16.6

Notes:

[21] - Confidence Interval and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as (1-hazard ratio)\*100

<b>Statistical analysis title</b>	Statistical Analysis 9
Comparison groups	Vilanterol 25 µg v Fluticasone furoate/vilanterol 100/25 µg
Number of subjects included in analysis	8239
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.545
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.938
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.761
upper limit	1.155

<b>Statistical analysis title</b>	Statistical Analysis 10
Comparison groups	Vilanterol 25 µg v Fluticasone furoate/vilanterol 100/25 µg

Number of subjects included in analysis	8239
Analysis specification	Pre-specified
Analysis type	superiority <sup>[22]</sup>
Parameter estimate	Percent reduction in risk of death
Point estimate	6.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.5
upper limit	23.9

Notes:

[22] - Confidence Interval and Estimated Value is presented for the percent reduction in risk of death at any time up to or on the CED, calculated as  $(1 - \text{hazard ratio}) \times 100$

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

On-treatment serious adverse events (SAEs) and non-serious adverse events (AEs) were collected from start of IP until IP discontinuation + 1 day (average of 2 study years).

Adverse event reporting additional description:

On-treatment SAEs and non-serious AEs are reported for safety population, comprised of all participants randomized to treatment who received at least one dose IP.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Participants (par.) received placeboXXXXXXXXTO DO

Reporting group title	Fluticasone furoate 100 µg
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Reporting group description:

To DO

Reporting group title	Vilanterol 25 µg
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Reporting group description:

TO DO

Reporting group title	Fluticasone furoate/vilanterol 100/25 µg
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Reporting group description:

TO DO

Serious adverse events	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg
Total subjects affected by serious adverse events			
subjects affected / exposed	918 / 4131 (22.22%)	929 / 4157 (22.35%)	972 / 4140 (23.48%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute myeloid leukaemia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	5 / 4131 (0.12%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of salivary gland			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adrenal adenoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiomyolipoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Astrocytoma			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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-cell lymphoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 neoplasm of adrenal gland			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of prostate			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bladder cancer			

subjects affected / exposed	0 / 4131 (0.00%)	5 / 4157 (0.12%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bladder cancer stage I, without cancer in situ			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Bladder transitional cell carcinoma			
subjects affected / exposed	3 / 4131 (0.07%)	3 / 4157 (0.07%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma stage 0			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Brain neoplasm malignant			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Breast cancer			



subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer in situ			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 metastatic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 I			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brenner tumour			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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	4 / 4131 (0.10%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 0
Bronchioloalveolar carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Choroid melanoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Colon cancer recurrent			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Colon cancer stage IV			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Colon neoplasm			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear neoplasm malignant			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid haemangioma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastric cancer			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Gastric cancer stage I			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 cancer stage III			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Head and neck cancer			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hepatic cancer metastatic			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatic neoplasm			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Laryngeal squamous cell carcinoma			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	5 / 4131 (0.12%)	3 / 4157 (0.07%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung adenocarcinoma stage IV			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung cancer metastatic			
subjects affected / exposed	2 / 4131 (0.05%)	5 / 4157 (0.12%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 3
Lung carcinoma cell type unspecified recurrent			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage 0			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage III			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	5 / 4131 (0.12%)	4 / 4157 (0.10%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Lung neoplasm malignant			
subjects affected / exposed	8 / 4131 (0.19%)	13 / 4157 (0.31%)	17 / 4140 (0.41%)
occurrences causally related to treatment / all	0 / 8	0 / 13	0 / 17
deaths causally related to treatment / all	0 / 3	0 / 7	0 / 8
Lung squamous cell carcinoma metastatic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung squamous cell carcinoma stage II			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 squamous cell carcinoma stage III			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung squamous cell carcinoma stage IV			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Lymphangiosis carcinomatosa			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic lymphoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of choroid			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Meningioma benign			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesothelioma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to adrenals			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to bone marrow			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 central nervous system			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Metastases to liver			
subjects affected / exposed	6 / 4131 (0.15%)	2 / 4157 (0.05%)	9 / 4140 (0.22%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 5
Metastases to lung			

subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Metastases to lymph nodes			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Metastases to peritoneum			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to skin			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to spleen			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 stomach			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastatic malignant melanoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myelodysplastic syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myeloproliferative disorder			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neoplasm prostate			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neuroendocrine tumour			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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-Hodgkin's lymphoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			

subjects affected / exposed	3 / 4131 (0.07%)	7 / 4157 (0.17%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 0
Non-small cell lung cancer stage I			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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-small cell lung cancer stage II			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer stage IIIA			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer stage IIIB			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Oesophageal adenocarcinoma			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Oesophageal carcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Oesophageal squamous cell carcinoma metastatic			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma stage II			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oral neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal squamous cell carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer metastatic			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ovarian germ cell teratoma benign			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian granulosa cell tumour			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	6 / 4131 (0.15%)	1 / 4157 (0.02%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Pancreatic carcinoma metastatic			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatic neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phyllodes tumour			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Polycythaemia vera			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Prostate cancer			

subjects affected / exposed	5 / 4131 (0.12%)	4 / 4157 (0.10%)	8 / 4140 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Prostate cancer metastatic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostate cancer recurrent			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Prostatic adenoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	3 / 4131 (0.07%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rectal adenoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rectal neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal cancer			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 cell carcinoma			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Renal neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 oncocytoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Round cell liposarcoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal cancer			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			



subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	4 / 4131 (0.10%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Small cell lung cancer metastatic			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Small intestine carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Spinal cord neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	6 / 4131 (0.15%)	6 / 4157 (0.14%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the cervix			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell lymphoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat cancer			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Thymoma malignant			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsil cancer			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyosarcoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvar adenocarcinoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			

subjects affected / exposed	10 / 4131 (0.24%)	8 / 4157 (0.19%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 3
Aortic arteriosclerosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dilatation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 disorder			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 dissection			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic thrombosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial disorder			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial occlusive disease			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial rupture			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial thrombosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arteriovenous fistula			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	0 / 4140 (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
Deep vein thrombosis			

subjects affected / exposed	6 / 4131 (0.15%)	5 / 4157 (0.12%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic microangiopathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Embolism			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	0 / 4131 (0.00%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	7 / 4131 (0.17%)	9 / 4157 (0.22%)	8 / 4140 (0.19%)
occurrences causally related to treatment / all	0 / 9	0 / 9	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hypertensive crisis			
subjects affected / exposed	3 / 4131 (0.07%)	5 / 4157 (0.12%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypertensive emergency			

subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Hypotension			
subjects affected / exposed	4 / 4131 (0.10%)	8 / 4157 (0.19%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery occlusion			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating atherosclerotic ulcer			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 arterial occlusive disease			

subjects affected / exposed	9 / 4131 (0.22%)	16 / 4157 (0.38%)	11 / 4140 (0.27%)
occurrences causally related to treatment / all	0 / 10	0 / 19	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	4 / 4131 (0.10%)	3 / 4157 (0.07%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	2 / 4131 (0.05%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral circulatory failure			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	4 / 4131 (0.10%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	1 / 4131 (0.02%)	8 / 4157 (0.19%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			



subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poor peripheral circulation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Raynaud's phenomenon			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renovascular hypertension			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary hypertension			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Subclavian artery occlusion			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery stenosis			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 steal syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thromboangiitis obliterans			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular occlusion			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 stenosis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasoconstriction			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous occlusion			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Venous thrombosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vessel perforation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Finger amputation			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee arthroplasty			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff repair			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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	2 / 4131 (0.05%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac death			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chest discomfort			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	16 / 4131 (0.39%)	10 / 4157 (0.24%)	8 / 4140 (0.19%)
occurrences causally related to treatment / all	0 / 18	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 1
Cyst			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	6 / 4131 (0.15%)	7 / 4157 (0.17%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 6	1 / 7	0 / 5
deaths causally related to treatment / all	0 / 6	1 / 7	0 / 5
Device defective			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device deployment issue			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device electrical finding			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device issue			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			

subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocution			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Impaired healing			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 ulcer			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device complication			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	2 / 4131 (0.05%)	3 / 4157 (0.07%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	4 / 4131 (0.10%)	5 / 4157 (0.12%)	10 / 4140 (0.24%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Pain			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	3 / 4131 (0.07%)	7 / 4157 (0.17%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 3	0 / 7	0 / 6
Sudden death			

subjects affected / exposed	20 / 4131 (0.48%)	14 / 4157 (0.34%)	17 / 4140 (0.41%)
occurrences causally related to treatment / all	0 / 20	0 / 14	0 / 17
deaths causally related to treatment / all	0 / 20	0 / 14	0 / 17
<b>Immune system disorders</b>			
<b>Anaphylactic reaction</b>			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaphylactic shock</b>			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
<b>Drug hypersensitivity</b>			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Food allergy</b>			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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>Hypersensitivity</b>			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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>Reproductive system and breast disorders</b>			
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	3 / 4131 (0.07%)	7 / 4157 (0.17%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Breast pain</b>			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 polyp			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fallopian tube cyst			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peyronie's disease			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine enlargement			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Acute pulmonary oedema			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	17 / 4131 (0.41%)	7 / 4157 (0.17%)	8 / 4140 (0.19%)
occurrences causally related to treatment / all	1 / 18	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 2
Atelectasis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial polyp			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchostenosis			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous lung disease			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	262 / 4131 (6.34%)	214 / 4157 (5.15%)	245 / 4140 (5.92%)
occurrences causally related to treatment / all	10 / 356	7 / 274	7 / 326
deaths causally related to treatment / all	0 / 6	0 / 6	0 / 4
Chronic respiratory failure			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	6 / 4131 (0.15%)	9 / 4157 (0.22%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	1 / 6	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dyspnoea at rest			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			

subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	2 / 4131 (0.05%)	8 / 4157 (0.19%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (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
Hypoxia			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 consolidation			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung infiltration			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 septum deviation			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (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
Pharyngeal cyst			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pickwickian syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	6 / 4131 (0.15%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	7 / 4131 (0.17%)	6 / 4157 (0.14%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary embolism			
subjects affected / exposed	10 / 4131 (0.24%)	12 / 4157 (0.29%)	17 / 4140 (0.41%)
occurrences causally related to treatment / all	0 / 10	0 / 14	0 / 17
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 5
Pulmonary fibrosis			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (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
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hilum mass			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 mass			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	2 / 4131 (0.05%)	4 / 4157 (0.10%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Respiratory distress			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	8 / 4131 (0.19%)	7 / 4157 (0.17%)	9 / 4140 (0.22%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 4
Sinus polyp			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol abuse			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Anxiety			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			



subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Confusional state			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Depression			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphoria			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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, visual			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			

subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Major depression			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	2 / 4131 (0.05%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia, paranoid type			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance abuse			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance-induced mood disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (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
Suicidal ideation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriogram coronary			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose fluctuation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose increased			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Blood urine present			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest X-ray abnormal			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 enzyme increased			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker increased			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic ulcer haemorrhage			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns third degree			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Cataract traumatic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical burn of skin			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical injury			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Comminuted fracture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 4131 (0.00%)	4 / 4157 (0.10%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery restenosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 vascular graft occlusion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dislocation of vertebra			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure via inhalation			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye contusion			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to anastomose			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	4 / 4131 (0.10%)	2 / 4157 (0.05%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	2 / 4131 (0.05%)	4 / 4157 (0.10%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	5 / 4131 (0.12%)	6 / 4157 (0.14%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fibula fracture			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Foot fracture			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal injury			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Head injury			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 haematoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	3 / 4131 (0.07%)	4 / 4157 (0.10%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			



subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal anastomosis complication			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint capsule rupture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Meniscus injury			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Muscle injury			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Overdose			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Patella fracture			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital contusion			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post laminectomy syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 haematoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			

subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Post procedural haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative hernia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative respiratory failure			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 complication			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 pneumonitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (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
Rib fracture			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Scar			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt thrombosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 compression fracture			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Traumatic haemothorax			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral injury			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve injury			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft occlusion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft thrombosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Wound evisceration			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Adrenogenital syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial septal defect			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyloric stenosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sturge-Weber syndrome			



subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitello-intestinal duct remnant			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 4131 (0.07%)	3 / 4157 (0.07%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute left ventricular failure			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myocardial infarction			
subjects affected / exposed	23 / 4131 (0.56%)	20 / 4157 (0.48%)	21 / 4140 (0.51%)
occurrences causally related to treatment / all	0 / 23	0 / 20	0 / 21
deaths causally related to treatment / all	0 / 5	0 / 6	0 / 4
Adams-Stokes syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Angina pectoris			
subjects affected / exposed	22 / 4131 (0.53%)	19 / 4157 (0.46%)	20 / 4140 (0.48%)
occurrences causally related to treatment / all	0 / 23	0 / 21	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	23 / 4131 (0.56%)	22 / 4157 (0.53%)	16 / 4140 (0.39%)
occurrences causally related to treatment / all	0 / 24	1 / 24	3 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	1 / 4131 (0.02%)	4 / 4157 (0.10%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 1
Arrhythmia supraventricular			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (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
Arteriosclerosis coronary artery			
subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	31 / 4131 (0.75%)	22 / 4157 (0.53%)	30 / 4140 (0.72%)
occurrences causally related to treatment / all	3 / 37	0 / 23	5 / 31
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial flutter			
subjects affected / exposed	6 / 4131 (0.15%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	1 / 6	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	3 / 4131 (0.07%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrioventricular block first degree			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
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	3 / 4131 (0.07%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bundle branch block left			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block right			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	9 / 4131 (0.22%)	9 / 4157 (0.22%)	11 / 4140 (0.27%)
occurrences causally related to treatment / all	0 / 9	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 7	0 / 8	0 / 9
Cardiac failure			
subjects affected / exposed	28 / 4131 (0.68%)	17 / 4157 (0.41%)	19 / 4140 (0.46%)
occurrences causally related to treatment / all	0 / 30	0 / 18	0 / 23
deaths causally related to treatment / all	0 / 8	0 / 4	0 / 5
Cardiac failure acute			
subjects affected / exposed	7 / 4131 (0.17%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 7	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 6	0 / 1	0 / 2
Cardiac failure chronic			
subjects affected / exposed	5 / 4131 (0.12%)	7 / 4157 (0.17%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 0
Cardiac failure congestive			
subjects affected / exposed	26 / 4131 (0.63%)	26 / 4157 (0.63%)	21 / 4140 (0.51%)
occurrences causally related to treatment / all	1 / 30	0 / 33	0 / 22
deaths causally related to treatment / all	0 / 5	0 / 4	0 / 2
Cardiac perforation			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac valve disease			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ventricular thrombosis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	11 / 4131 (0.27%)	9 / 4157 (0.22%)	11 / 4140 (0.27%)
occurrences causally related to treatment / all	0 / 11	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 10	0 / 9	0 / 10
Cardiogenic shock			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Cardiomegaly			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	1 / 3	0 / 3
Cardiovascular disorder			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Conduction disorder			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cor pulmonale			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	22 / 4131 (0.53%)	14 / 4157 (0.34%)	25 / 4140 (0.60%)
occurrences causally related to treatment / all	0 / 23	0 / 14	0 / 26
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Coronary artery insufficiency			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery occlusion			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery thrombosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary ostial stenosis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastolic dysfunction			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrasystoles			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	4 / 4131 (0.10%)	3 / 4157 (0.07%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Left ventricular dysfunction			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	3 / 4131 (0.07%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			

subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mitral valve stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial fibrosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	24 / 4131 (0.58%)	32 / 4157 (0.77%)	26 / 4140 (0.63%)
occurrences causally related to treatment / all	0 / 24	1 / 35	0 / 27
deaths causally related to treatment / all	0 / 10	1 / 17	0 / 16
Myocardial ischaemia			
subjects affected / exposed	7 / 4131 (0.17%)	8 / 4157 (0.19%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	1 / 7	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Myocardial necrosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			



subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rheumatic heart disease			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinoatrial block			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	3 / 4131 (0.07%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachyarrhythmia			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia paroxysmal			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricle rupture			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ventricular tachycardia			
subjects affected / exposed	0 / 4131 (0.00%)	3 / 4157 (0.07%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Amyotrophic lateral sclerosis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aphasia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal ganglia infarction			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basilar artery occlusion			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain mass			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Brain stem infarction			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 stem ischaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain stem stroke			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arteriosclerosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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 disease			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	4 / 4131 (0.10%)	6 / 4157 (0.14%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar atrophy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral atrophy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebral haemorrhage			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	5 / 4131 (0.12%)	6 / 4157 (0.14%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cerebral ischaemia			

subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Cerebral ventricle dilatation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	16 / 4131 (0.39%)	11 / 4157 (0.26%)	11 / 4140 (0.27%)
occurrences causally related to treatment / all	0 / 16	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 8	0 / 2	0 / 3
Cerebrovascular disorder			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 radiculopathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Complex partial seizures			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic neuropathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplegia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Encephalopathy			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	4 / 4131 (0.10%)	4 / 4157 (0.10%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 4
Headache			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Hemiparesis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			



subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paralysis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ischaemic cerebral infarction			

subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Ischaemic stroke			
subjects affected / exposed	19 / 4131 (0.46%)	15 / 4157 (0.36%)	14 / 4140 (0.34%)
occurrences causally related to treatment / all	0 / 19	0 / 15	1 / 16
deaths causally related to treatment / all	0 / 3	0 / 2	1 / 3
Lacunar infarction			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lumbar radiculopathy			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Meralgia paraesthetica			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 sensory neuropathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postictal paralysis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radicular syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacral radiculopathy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitic myelopathy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Syncope			
subjects affected / exposed	6 / 4131 (0.15%)	7 / 4157 (0.17%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic outlet syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	7 / 4131 (0.17%)	13 / 4157 (0.31%)	16 / 4140 (0.39%)
occurrences causally related to treatment / all	0 / 7	1 / 13	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Trigeminal neuralgia			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular parkinsonism			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (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
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Anaemia			
subjects affected / exposed	8 / 4131 (0.19%)	6 / 4157 (0.14%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow oedema			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercoagulation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersplenism			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 mediastinal			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic vein thrombosis			



subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous haematoma			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Meniere's disease			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinnitus			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tympanic membrane perforation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 4131 (0.00%)	4 / 4157 (0.10%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			

subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	1 / 4131 (0.02%)	5 / 4157 (0.12%)	8 / 4140 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract cortical			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridodonesis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens dislocation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular hypertension			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 detachment			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal disorder			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 tear			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vascular disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous prolapse			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal incarcerated hernia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 4131 (0.00%)	3 / 4157 (0.07%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			

subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Anal fissure			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 fistula			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Colitis			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (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
Colitis ischaemic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 ulcerative			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Crohn's disease			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	4 / 4131 (0.10%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dieulafoy's vascular malformation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			

subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous fistula			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive duodenitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral hernia			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Gastric ulcer perforation			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenal haemorrhage			



subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 disorder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	4 / 4131 (0.10%)	4 / 4157 (0.10%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival bleeding			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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			

subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Inflammatory bowel disease			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	8 / 4131 (0.19%)	4 / 4157 (0.10%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal infarction			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	2 / 4131 (0.05%)	3 / 4157 (0.07%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal polyp			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Large intestine polyp			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	0 / 4140 (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
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	0 / 4140 (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
Mouth ulceration			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Noninfective sialoadenitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedematous pancreatitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis ulcerative			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 necrosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	2 / 4131 (0.05%)	4 / 4157 (0.10%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatitis acute			
subjects affected / exposed	4 / 4131 (0.10%)	7 / 4157 (0.17%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pancreatitis chronic			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			

subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal adhesions			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal perforation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 haemorrhage			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Small intestinal obstruction			

subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small intestinal perforation			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 gastrointestinal haemorrhage			
subjects affected / exposed	3 / 4131 (0.07%)	5 / 4157 (0.12%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Varices oesophageal			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			

subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Cholangitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	7 / 4131 (0.17%)	4 / 4157 (0.10%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	5 / 4131 (0.12%)	3 / 4157 (0.07%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic hepatitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic cirrhosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			



subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic function abnormal			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Hepatitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal failure			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post cholecystectomy syndrome			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (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
Erythema nodosum			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic angioedema			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathic ulcer			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Photosensitivity reaction			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 lesion			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin maceration			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 oedema			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin sensitisation			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	0 / 4140 (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
Urticaria			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	7 / 4131 (0.17%)	7 / 4157 (0.17%)	8 / 4140 (0.19%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Acute prerenal failure			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Azotaemia			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neck sclerosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	4 / 4131 (0.10%)	6 / 4157 (0.14%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic nephropathy			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (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
Dysuria			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	4 / 4131 (0.10%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nocturia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive uropathy			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 cyst			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 failure			

subjects affected / exposed	2 / 4131 (0.05%)	7 / 4157 (0.17%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal mass			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder polyp			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 4131 (0.02%)	4 / 4157 (0.10%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Addison's disease			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 / 4131 (0.02%)	0 / 4157 (0.00%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primary hyperaldosteronism			



subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthrofibrosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone lesion			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coccydynia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Fibromyalgia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture nonunion			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Intervertebral disc protrusion			
subjects affected / exposed	3 / 4131 (0.07%)	3 / 4157 (0.07%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	4 / 4131 (0.10%)	1 / 4157 (0.02%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	14 / 4131 (0.34%)	10 / 4157 (0.24%)	11 / 4140 (0.27%)
occurrences causally related to treatment / all	0 / 17	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (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
Osteonecrosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthrititis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 disorder			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			

subjects affected / exposed	3 / 4131 (0.07%)	0 / 4157 (0.00%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 hepatitis B			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Appendicitis			
subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Appendicitis perforated			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical mycobacterial infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 abscess			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			



subjects affected / exposed	12 / 4131 (0.29%)	9 / 4157 (0.22%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	1 / 15	2 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	3 / 4131 (0.07%)	8 / 4157 (0.19%)	7 / 4140 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	5 / 4131 (0.12%)	10 / 4157 (0.24%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis infective			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 4131 (0.00%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	4 / 4131 (0.10%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolitic pneumonia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysematous cystitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	0 / 4140 (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
Escherichia sepsis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder empyema			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	3 / 4131 (0.07%)	3 / 4157 (0.07%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	6 / 4131 (0.15%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis staphylococcal			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 fungal infection			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft infection			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Haematoma infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster disseminated			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site abscess			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bites			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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 skin ulcer			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	4 / 4131 (0.10%)	6 / 4157 (0.14%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 4	2 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	0 / 4140 (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
Intervertebral discitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	8 / 4131 (0.19%)	8 / 4157 (0.19%)	5 / 4140 (0.12%)
occurrences causally related to treatment / all	1 / 9	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	2 / 4131 (0.05%)	4 / 4157 (0.10%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph gland infection			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node abscess			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningoencephalitis herpetic			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Neuroborreliosis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 4131 (0.00%)	4 / 4157 (0.10%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa bacterial			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pharyngotonsillitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			



subjects affected / exposed	113 / 4131 (2.74%)	121 / 4157 (2.91%)	90 / 4140 (2.17%)
occurrences causally related to treatment / all	3 / 128	13 / 145	3 / 99
deaths causally related to treatment / all	0 / 8	2 / 10	0 / 3
Pneumonia bacterial			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia moraxella			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia streptococcal			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 tuberculosis			

subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purulent discharge			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelocystitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
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 acute			
subjects affected / exposed	2 / 4131 (0.05%)	2 / 4157 (0.05%)	0 / 4140 (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
Respiratory tract infection			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (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
Salmonella sepsis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
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 abscess			

subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	10 / 4131 (0.24%)	4 / 4157 (0.10%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 2
Septic shock			
subjects affected / exposed	5 / 4131 (0.12%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 1
Sialoadenitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis septic			

subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic shock syndrome			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Tuberculosis			
subjects affected / exposed	1 / 4131 (0.02%)	3 / 4157 (0.07%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tuberculous pleurisy			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	3 / 4131 (0.07%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	5 / 4131 (0.12%)	7 / 4157 (0.17%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			

subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 4131 (0.02%)	1 / 4157 (0.02%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (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
Cachexia			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	3 / 4140 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	5 / 4131 (0.12%)	1 / 4157 (0.02%)	6 / 4140 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	4 / 4131 (0.10%)	6 / 4157 (0.14%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 4131 (0.02%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercholesterolaemia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 4131 (0.00%)	2 / 4157 (0.05%)	0 / 4140 (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
Hyperkalaemia			
subjects affected / exposed	3 / 4131 (0.07%)	0 / 4157 (0.00%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	4 / 4131 (0.10%)	3 / 4157 (0.07%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	2 / 4131 (0.05%)	0 / 4157 (0.00%)	1 / 4140 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 4131 (0.05%)	1 / 4157 (0.02%)	4 / 4140 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
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	1 / 4131 (0.02%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 4131 (0.00%)	0 / 4157 (0.00%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 4131 (0.02%)	2 / 4157 (0.05%)	2 / 4140 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin D deficiency			
subjects affected / exposed	0 / 4131 (0.00%)	1 / 4157 (0.02%)	0 / 4140 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Fluticasone furoate/vilanterol 100/25 µg		
Total subjects affected by serious adverse events			
subjects affected / exposed	961 / 4140 (23.21%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			



subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma gastric			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of salivary gland			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adrenal adenoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angiomyolipoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Astrocytoma			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign lung neoplasm			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of adrenal gland			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of bladder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of prostate			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bile duct cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			

subjects affected / exposed	5 / 4140 (0.12%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Bladder cancer stage I, without cancer in situ				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder neoplasm				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma recurrent				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma stage 0				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm malignant				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Breast cancer				

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Breast cancer in situ			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer metastatic			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Breast cancer stage I			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brenner tumour			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial carcinoma			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchioloalveolar carcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervix carcinoma			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangiocarcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Choroid melanoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Colon cancer recurrent			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer stage IV			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon neoplasm			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colorectal cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear neoplasm malignant			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid haemangioma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric cancer stage I			

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric cancer stage III				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal stromal tumour				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal tract adenoma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glioblastoma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head and neck cancer				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cancer				
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic neoplasm				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatocellular carcinoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inflammatory pseudotumour			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 4140 (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	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Keratoacanthoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal cancer			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laryngeal squamous cell carcinoma			



subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma stage IV			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung cancer metastatic			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Lung carcinoma cell type unspecified recurrent			

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung carcinoma cell type unspecified stage 0				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung carcinoma cell type unspecified stage III				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lung carcinoma cell type unspecified stage IV				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lung neoplasm				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Lung neoplasm malignant				
subjects affected / exposed	10 / 4140 (0.24%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 2			
Lung squamous cell carcinoma metastatic				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung squamous cell carcinoma stage II				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Lung squamous cell carcinoma stage III				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung squamous cell carcinoma stage IV				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphangiosis carcinomatosa				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphocytic lymphoma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of ampulla of Vater				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of choroid				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningioma				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Meningioma benign				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric neoplasm				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesothelioma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to adrenals				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to bone				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to bone marrow				
subjects affected / exposed	0 / 4140 (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	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Metastases to liver				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 2			
Metastases to lung				

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to lymph nodes			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to peritoneum			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to skin			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to spine			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to spleen			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to stomach			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic malignant melanoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic neoplasm			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myeloproliferative disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm malignant			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm prostate			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuroendocrine tumour			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer			

subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer stage I				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer stage II				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer stage IIIA				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Non-small cell lung cancer stage IIIB				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal adenocarcinoma				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal carcinoma				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma metastatic				

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma stage II				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral neoplasm				
subjects affected / exposed	0 / 4140 (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	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer metastatic				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian germ cell teratoma benign				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian granulosa cell tumour				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 2			
Pancreatic carcinoma metastatic				



subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic neoplasm				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Papillary cystadenoma lymphomatosum				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Papillary thyroid cancer				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Phyllodes tumour				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pituitary tumour benign				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plasma cell myeloma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polycythaemia vera				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				

subjects affected / exposed	11 / 4140 (0.27%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Prostate cancer metastatic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer recurrent			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic adenoma			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal adenoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal neoplasm			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cancer			

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Renal neoplasm			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal oncocytoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal neoplasm			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Round cell liposarcoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schwannoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scrotal cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin cancer			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 4		
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestine carcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord neoplasm			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	12 / 4140 (0.29%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 6		
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of the cervix			

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the tongue				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
T-cell lymphoma				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Throat cancer				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thymoma malignant				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Thyroid neoplasm				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tongue neoplasm malignant stage unspecified				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsil cancer				

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine cancer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyosarcoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord neoplasm			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vulvar adenocarcinoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm			

subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Aortic aneurysm rupture			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aortic arteriosclerosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic dilatation			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aortic stenosis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Aortic thrombosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arterial disorder			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial occlusive disease			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Arterial rupture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arterial stenosis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arterial thrombosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Arteriovenous fistula			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Deep vein thrombosis			



subjects affected / exposed	5 / 4140 (0.12%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Diabetic microangiopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extremity necrosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral artery occlusion			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	11 / 4140 (0.27%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Hypertensive emergency			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Iliac artery occlusion			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intermittent claudication			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leriche syndrome			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penetrating atherosclerotic ulcer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			

subjects affected / exposed	5 / 4140 (0.12%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Peripheral artery aneurysm			
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral artery thrombosis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Peripheral circulatory failure			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral embolism			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Peripheral vascular disorder			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Peripheral venous disease			

subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Phlebitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Poor peripheral circulation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Raynaud's phenomenon			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renovascular hypertension			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Secondary hypertension			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock haemorrhagic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subclavian artery occlusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subclavian artery stenosis			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subclavian steal syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Temporal arteritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thromboangiitis obliterans			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular occlusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular stenosis			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vasoconstriction			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Venous occlusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis limb			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vessel perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Finger amputation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Knee arthroplasty			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff repair			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgery			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac death			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	16 / 4140 (0.39%)		
occurrences causally related to treatment / all	1 / 18		
deaths causally related to treatment / all	0 / 0		
Cyst			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Death			

subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 7		
Device defective			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device deployment issue			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device electrical finding			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device failure			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device issue			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			



subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electrocution			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gait disturbance			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised oedema			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hernia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impaired healing			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza like illness			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic ulcer			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medical device complication			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multi-organ failure			
subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 5		
Non-cardiac chest pain			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sudden cardiac death			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sudden death			

subjects affected / exposed	20 / 4140 (0.48%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 20		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaphylactic shock			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Drug hypersensitivity			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Food allergy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	0 / 4140 (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	5 / 4140 (0.12%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Breast pain			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Cervical polyp			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervix disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial hyperplasia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fallopian tube cyst			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peyronie's disease			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatomegaly			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine enlargement			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Acute pulmonary oedema				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	12 / 4140 (0.29%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Bronchial polyp				
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiectasis				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchostenosis				

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bullous lung disease				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	189 / 4140 (4.57%)			
occurrences causally related to treatment / all	6 / 237			
deaths causally related to treatment / all	1 / 8			
Chronic respiratory failure				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	3 / 4140 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Dyspnoea at rest				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Emphysema				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epistaxis				

subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Haemothorax			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrothorax			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercapnia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laryngeal disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal polyp			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung consolidation			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Lung infiltration			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasal septum deviation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septum disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngeal cyst			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pickwickian syndrome			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			



subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Pleurisy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pneumothorax spontaneous			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary congestion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	13 / 4140 (0.31%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 6		
Pulmonary fibrosis			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary hilum mass			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary hypertension			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Respiratory distress			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory failure			
subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 3		
Sinus polyp			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vocal cord disorder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Affective disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcohol abuse			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcoholism			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder			

subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Completed suicide				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Drug abuse				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysphoria				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hallucination, visual				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Insomnia				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychogenic seizure			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schizoaffective disorder			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Schizophrenia, paranoid type			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Substance abuse			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Substance-induced mood disorder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicidal behaviour			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriogram coronary			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood glucose fluctuation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood glucose increased			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood urine present			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest X-ray abnormal			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic enzyme increased			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Liver function test abnormal			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acetabulum fracture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anastomotic ulcer haemorrhage			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain contusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burns third degree			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract traumatic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chemical burn of skin			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chemical injury			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			



subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Comminuted fracture			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Concussion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Coronary artery restenosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary vascular graft occlusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dislocation of vertebra			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Exposure via inhalation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye contusion			

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to anastomose				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	3 / 4140 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	8 / 4140 (0.19%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Forearm fracture				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal injury			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gun shot wound			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic haematoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal anastomosis complication			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint capsule rupture			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb crushing injury			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb traumatic amputation			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscle injury			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscle rupture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Patella fracture			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital contusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periprosthetic fracture			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post laminectomy syndrome			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haematoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematuria			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative hernia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative respiratory failure			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural complication			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural pain			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radiation pneumonitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radius fracture			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scar			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seroma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Shunt thrombosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Soft tissue injury			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			



subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sternal fracture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Tendon rupture			
subjects affected / exposed	0 / 4140 (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 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic haematoma			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic haemothorax			

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haemorrhage				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral injury				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VIth nerve injury				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular graft occlusion				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular graft thrombosis				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular pseudoaneurysm				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound evisceration			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Adrenogenital syndrome			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial septal defect			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocele			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyloric stenosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sturge-Weber syndrome			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitello-intestinal duct remnant			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	5 / 4140 (0.12%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Acute left ventricular failure			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Acute myocardial infarction			
subjects affected / exposed	28 / 4140 (0.68%)		
occurrences causally related to treatment / all	2 / 30		
deaths causally related to treatment / all	1 / 7		
Adams-Stokes syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina pectoris			
subjects affected / exposed	12 / 4140 (0.29%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	23 / 4140 (0.56%)		
occurrences causally related to treatment / all	1 / 23		
deaths causally related to treatment / all	0 / 0		
Aortic valve disease			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic valve incompetence			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 2		
Arrhythmia supraventricular			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis coronary artery			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Atrial fibrillation			
subjects affected / exposed	32 / 4140 (0.77%)		
occurrences causally related to treatment / all	4 / 36		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Atrial tachycardia			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Atrioventricular block complete			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block first degree			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block second degree			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradyarrhythmia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bundle branch block left			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Bundle branch block right			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Cardiac failure			
subjects affected / exposed	28 / 4140 (0.68%)		
occurrences causally related to treatment / all	1 / 31		
deaths causally related to treatment / all	0 / 7		
Cardiac failure acute			
subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 5		
Cardiac failure chronic			
subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 2		
Cardiac failure congestive			
subjects affected / exposed	30 / 4140 (0.72%)		
occurrences causally related to treatment / all	0 / 33		
deaths causally related to treatment / all	0 / 1		
Cardiac perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac valve disease			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac ventricular thrombosis			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	5 / 4140 (0.12%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 4		
Cardiogenic shock			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomegaly			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Cardiopulmonary failure			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Cardiovascular disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiovascular insufficiency			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conduction disorder			



subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cor pulmonale			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	24 / 4140 (0.58%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 2		
Coronary artery insufficiency			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Coronary artery thrombosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary ostial stenosis			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diastolic dysfunction			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extrasystoles			
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Left ventricular dysfunction			
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular hypertrophy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			

subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Mitral valve stenosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial fibrosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	24 / 4140 (0.58%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 7		
Myocardial ischaemia			
subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Myocardial necrosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocarditis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulseless electrical activity			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rheumatic heart disease			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Right ventricular failure			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinoatrial block			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus bradycardia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sinus tachycardia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular extrasystoles			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachyarrhythmia			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia paroxysmal			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricle rupture			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Amyotrophic lateral sclerosis			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal ganglia infarction			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basilar artery occlusion			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain injury			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Brain mass			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain stem infarction			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain stem ischaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain stem stroke			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid arteriosclerosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery aneurysm			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery disease			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid artery occlusion			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cerebellar atrophy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral atrophy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haematoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	7 / 4140 (0.17%)		
occurrences causally related to treatment / all	1 / 7		
deaths causally related to treatment / all	0 / 1		
Cerebral ischaemia			



subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral ventricle dilatation			
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	18 / 4140 (0.43%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 6		
Cerebrovascular disorder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical myelopathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervical radiculopathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cognitive disorder			

subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Coma				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Complex partial seizures				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dementia				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dementia Alzheimer's type				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic neuropathy				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diplegia				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				

subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 4140 (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 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic cerebral infarction				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic stroke				
subjects affected / exposed	3 / 4140 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Headache				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hemiparesis				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hemiplegia				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic encephalopathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
IIIrd nerve paralysis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intercostal neuralgia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial aneurysm			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraventricular haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic cerebral infarction			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	19 / 4140 (0.46%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 3		
Lacunar infarction			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meralgia paraesthetica			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple sclerosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myasthenia gravis			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nerve compression			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neurological symptom			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuropathy peripheral			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Normal pressure hydrocephalus			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postictal paralysis				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Radicular syndrome				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiculopathy				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sacral radiculopathy				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Speech disorder				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord disorder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondylitic myelopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	10 / 4140 (0.24%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Thoracic outlet syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient global amnesia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Trigeminal neuralgia			



subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular encephalopathy			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular parkinsonism			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebral artery stenosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar insufficiency			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	5 / 4140 (0.12%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Bone marrow oedema			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic anaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercoagulation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersplenism			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microcytic anaemia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polycythaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic vein thrombosis			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spontaneous haematoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Meniere's disease			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tinnitus			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular disorder			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blindness unilateral			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract			
subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Cataract cortical			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diplopia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid ptosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glaucoma			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iridodonesis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lens dislocation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ocular hypertension			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ocular ischaemic syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal artery occlusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal tear			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal vascular disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous prolapse			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute abdomen			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fistula			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic gastritis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis ulcerative			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			



subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Crohn's disease				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dental caries				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	6 / 4140 (0.14%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Dieulafoy's vascular malformation				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal haemorrhagic				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal stenosis				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspepsia			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocutaneous fistula			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterovesical fistula			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erosive duodenitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral hernia			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric haemorrhage			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 4140 (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 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastritis erosive			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis haemorrhagic			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroduodenal haemorrhage			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Gastrointestinal necrosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gingival bleeding			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematochezia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ileus paralytic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inflammatory bowel disease			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	8 / 4140 (0.19%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia strangulated			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal infarction			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal ischaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal polyp			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal haemorrhage			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Irritable bowel syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestinal stenosis			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mechanical ileus			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Noninfective sialoadenitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedematous pancreatitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophagitis ulcerative			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic necrosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pancreatitis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pancreatitis chronic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer			



subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer perforation			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritoneal adhesions			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritoneal haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritoneal perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Proctitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal perforation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Varices oesophageal			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bile duct stenosis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cholecystitis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	8 / 4140 (0.19%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Chronic hepatitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hepatic function abnormal			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic steatosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatorenal failure			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hepatorenal syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaundice cholestatic			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver injury			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Portal hypertension			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermal cyst			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis allergic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis exfoliative			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic foot			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erythema nodosum			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Idiopathic angioedema			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuropathic ulcer			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Photosensitivity reaction			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pruritus			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin lesion			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin maceration			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin oedema			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin sensitisation			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 2		
Acute prerenal failure			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Azotaemia			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder neck sclerosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder stenosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus bladder			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus ureteric			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Cystitis haemorrhagic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic nephropathy			



subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysuria			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Nocturia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructive uropathy			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prerenal failure			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cyst			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal mass			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary bladder polyp			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Addison's disease			

subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adrenal insufficiency			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune thyroiditis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basedow's disease			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Primary hyperaldosteronism			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthrofibrosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Bone lesion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical spinal stenosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chondrocalcinosis pyrophosphate			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coccydynia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Costochondritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dupuytren's contracture			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fibromyalgia			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Foot deformity			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture nonunion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gouty arthritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc degeneration			

subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Joint effusion			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Muscle haemorrhage			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			

subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Myopathy				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	8 / 4140 (0.19%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Osteochondrosis				
subjects affected / exposed	3 / 4140 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periarthritis				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polyarthrititis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polymyalgia rheumatica			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rheumatoid arthritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff syndrome			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scoliosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal column stenosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal disorder			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal pain			



subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spondylitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic lupus erythematosus			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendonitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			

subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess intestinal			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess limb			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute hepatitis B			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute sinusitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebiasis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atypical mycobacterial infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary sepsis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary tract infection			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast abscess			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			

subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Bronchitis bacterial			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	6 / 4140 (0.14%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Cholangitis infective			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis infective			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diabetic foot infection			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea infectious			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Embolic pneumonia			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Emphysematous cystitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis			

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Endophthalmitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epididymitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder empyema			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gangrene			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Gastroenteritis			

subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis staphylococcal				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal fungal infection				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Graft infection				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma infection				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis A				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis C				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis E				

subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	2 / 4140 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Herpes zoster disseminated				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incision site abscess				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected bites				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	6 / 4140 (0.14%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Influenza				



subjects affected / exposed	4 / 4140 (0.10%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Intervertebral discitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia			
subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 1		
Lower respiratory tract infection			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lung abscess			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymph gland infection			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymph node abscess			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningoencephalitis herpetic			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Necrotising fasciitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuroborreliosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Orchitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis externa bacterial			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parainfluenzae virus infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pharyngotonsillitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumococcal infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	123 / 4140 (2.97%)		
occurrences causally related to treatment / all	11 / 140		
deaths causally related to treatment / all	0 / 14		
Pneumonia bacterial			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia haemophilus			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia moraxella			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia staphylococcal			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudomembranous colitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			

subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Purulent discharge			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelocystitis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salmonella sepsis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Scrotal abscess			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	8 / 4140 (0.19%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
Septic shock			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Sialoadenitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis septic			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxic shock syndrome			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Tuberculous pleurisy			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	9 / 4140 (0.22%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Urinary tract infection bacterial			

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	3 / 4140 (0.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Vestibular neuronitis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral myocarditis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	2 / 4140 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cachexia			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Decreased appetite			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			



subjects affected / exposed	3 / 4140 (0.07%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus inadequate control				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gout				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercholesterolaemia				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				

subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertriglyceridaemia				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	4 / 4140 (0.10%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	1 / 4140 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malnutrition				
subjects affected / exposed	0 / 4140 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				

subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Obesity</b>			
subjects affected / exposed	1 / 4140 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Type 2 diabetes mellitus</b>			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Vitamin D deficiency</b>			
subjects affected / exposed	0 / 4140 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

<b>Non-serious adverse events</b>	Placebo	Fluticasone furoate 100 µg	Vilanterol 25 µg
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	1862 / 4131 (45.07%)	1941 / 4157 (46.69%)	1827 / 4140 (44.13%)
<b>Vascular disorders</b>			
Hypertension			
subjects affected / exposed	129 / 4131 (3.12%)	138 / 4157 (3.32%)	124 / 4140 (3.00%)
occurrences (all)	192	189	194
<b>Nervous system disorders</b>			
Headache			
subjects affected / exposed	308 / 4131 (7.46%)	332 / 4157 (7.99%)	327 / 4140 (7.90%)
occurrences (all)	585	686	614
<b>Respiratory, thoracic and mediastinal disorders</b>			
Chronic obstructive pulmonary disease			
subjects affected / exposed	969 / 4131 (23.46%)	939 / 4157 (22.59%)	938 / 4140 (22.66%)
occurrences (all)	1731	1517	1689
<b>Cough</b>			

subjects affected / exposed occurrences (all)	254 / 4131 (6.15%) 338	224 / 4157 (5.39%) 259	215 / 4140 (5.19%) 285
Dyspnoea subjects affected / exposed occurrences (all)	172 / 4131 (4.16%) 254	185 / 4157 (4.45%) 233	132 / 4140 (3.19%) 195
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	140 / 4131 (3.39%) 170	168 / 4157 (4.04%) 249	162 / 4140 (3.91%) 209
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	165 / 4131 (3.99%) 228	184 / 4157 (4.43%) 229	168 / 4140 (4.06%) 226
Influenza subjects affected / exposed occurrences (all)	118 / 4131 (2.86%) 147	116 / 4157 (2.79%) 160	122 / 4140 (2.95%) 162
Nasopharyngitis subjects affected / exposed occurrences (all)	310 / 4131 (7.50%) 414	366 / 4157 (8.80%) 536	352 / 4140 (8.50%) 478
Upper respiratory tract infection subjects affected / exposed occurrences (all)	194 / 4131 (4.70%) 271	240 / 4157 (5.77%) 340	212 / 4140 (5.12%) 289

<b>Non-serious adverse events</b>	Fluticasone furoate/vilanterol 100/25 µg		
Total subjects affected by non-serious adverse events subjects affected / exposed	1761 / 4140 (42.54%)		
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	152 / 4140 (3.67%) 214		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	291 / 4140 (7.03%) 536		
Respiratory, thoracic and mediastinal disorders			

Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	779 / 4140 (18.82%) 1187		
Cough subjects affected / exposed occurrences (all)	206 / 4140 (4.98%) 264		
Dyspnoea subjects affected / exposed occurrences (all)	125 / 4140 (3.02%) 160		
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	173 / 4140 (4.18%) 235		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	166 / 4140 (4.01%) 223		
Influenza subjects affected / exposed occurrences (all)	137 / 4140 (3.31%) 192		
Nasopharyngitis subjects affected / exposed occurrences (all)	367 / 4140 (8.86%) 567		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	262 / 4140 (6.33%) 362		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 January 2011	Amendment no.01: Revised exclusion criteria regarding severe heart failure to include subjects with an implantable cardiac defibrillator (ICD) and provided clarification regarding disease related events/outcomes which would not be subject to expedited reporting.
18 February 2011	Amendment no.02: Revised the Run in period
30 April 2013	Amendment no.03: Added efficacy endpoints (cardiovascular procedures and change from baseline in forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC) and clarified wording regarding washout of prohibited medications.
17 April 2014	Amendment no.04: Applied only to sites in Korea and revised the statement regarding use of non cardioselective beta blockers introduced in Amendment 03
07 May 2015	Amendment no.05: Revised the list of biomarkers (other endpoint), added time to first COPD exacerbation and deleted the analysis of time to COPD related death, and updated other treatment comparisons of interest.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported