



## Clinical trial results:

**Ensayo clínico de vacunación fase III, aleatorizado, observador-ciego, controlado con placebo, multicéntrico para evaluar la eficacia profiláctica, seguridad e inmunogenicidad de la vacuna gE/AS01B de GSK Biologicals administrada por vía intramuscular con un esquema de 0, 2 meses en adultos de 70 años y mayores.**

### Summary

EudraCT number	2009-015791-94
Trial protocol	ES FI DE GB SE EE FR IT CZ
Global end of trial date	24 July 2015

### Results information

Result version number	v1
This version publication date	08 August 2016
First version publication date	08 August 2016

### Trial information

#### Trial identification

Sponsor protocol code	113077
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02723773
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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	14 January 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	24 July 2015
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

- Zoster-022 study:  
To evaluate vaccine efficacy (VE) in the prevention of herpes Zoster (HZ) compared to placebo in adults  $\geq 70$  years of age (YOA), as measured by the reduction in HZ risk.
- Zoster-006 and Zoster-022 pooled studies:  
To evaluate VE in the prevention of postherpetic neuralgia (PHN) compared to placebo in subjects  $\geq 70$  YOA across both Phase III studies.  
To consolidate VE estimation in the prevention of HZ compared to placebo in subjects  $\geq 70$  YOA across both Phase III studies.

Protection of trial subjects:

The vaccine/product recipients were to be observed closely for at least 30 minutes, with appropriate medical treatment readily available in case of a rare anaphylactic reaction following the administration of vaccine/product. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed-up for 30 days after the last vaccination/product administration.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 August 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	United States: 1879
Country: Number of subjects enrolled	Australia: 309
Country: Number of subjects enrolled	Brazil: 627
Country: Number of subjects enrolled	Canada: 802
Country: Number of subjects enrolled	Czech Republic: 321
Country: Number of subjects enrolled	Estonia: 1015
Country: Number of subjects enrolled	Finland: 1705
Country: Number of subjects enrolled	France: 575
Country: Number of subjects enrolled	Germany: 1202
Country: Number of subjects enrolled	Hong Kong: 180
Country: Number of subjects enrolled	Italy: 109
Country: Number of subjects enrolled	Japan: 511
Country: Number of subjects enrolled	Korea, Republic of: 528
Country: Number of subjects enrolled	Mexico: 453

Country: Number of subjects enrolled	Spain: 934
Country: Number of subjects enrolled	Sweden: 961
Country: Number of subjects enrolled	Taiwan: 1110
Country: Number of subjects enrolled	United Kingdom: 692
Worldwide total number of subjects	13913
EEA total number of subjects	7514

Notes:

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### 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)	13913
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

### Pre-assignment period milestones

Number of subjects started	13913
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Number of subjects completed	13900
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### Pre-assignment subject non-completion reasons

Reason: Number of subjects	No vaccination received: 13
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### Period 1

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

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Zoster-022 GSK1437173A Group
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Arm description:

Subjects receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Arm type	Experimental
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Investigational medicinal product name	GSK1437173A
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Powder and solvent for suspension for injection
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Routes of administration	Intramuscular use
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Dosage and administration details:

The study product was administered according to a 0, 2 month schedule.

<b>Arm title</b>	Zoster-022 Placebo Group
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Arm description:

Subjects receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Arm type	Placebo
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Investigational medicinal product name	Placebo
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Investigational medicinal product code	
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Other name	Saline solution
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Pharmaceutical forms	Solution for injection
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Routes of administration	Intramuscular use
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Dosage and administration details:

The study product was administered according to a 0, 2 month schedule.

<b>Number of subjects in period 1<sup>[1]</sup></b>	<b>Zoster-022 GSK1437173A Group</b>	<b>Zoster-022 Placebo Group</b>
Started	6950	6950
Completed	5770	5761
Not completed	1180	1189
Lack of time	1	-
Patient not eligible	-	1
Sponsor study termination	1	-
No reason from the subject	-	1
Health issues	61	56
Suspected HZ Episode	-	2
Site closure	18	20
Serious Adverse Event	459	487
Consent withdrawn by subject	396	401
Page entered in error	-	1
Non-Serious Adverse Event	47	15
Personal reason	10	4
Missed visit	1	-
Investigator decision	-	2
Migrated/moved from study area	51	46
Screening criteria unmet	1	-
Lost to follow-up	124	140
Protocol deviation	10	12
Unknown completion status	-	1

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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: Out of the 13913 subjects enrolled in the trial, 13 were assigned participant codes but did not receive vaccination, hence were excluded from study start.

## Baseline characteristics

### Reporting groups

Reporting group title	Zoster-022 GSK1437173A Group
Reporting group description: Subjects receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Reporting group title	Zoster-022 Placebo Group
Reporting group description: Subjects receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.	

Reporting group values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group	Total
Number of subjects	6950	6950	13900
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years			
arithmetic mean	75.6	75.6	
standard deviation	± 4.7	± 4.7	-
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	3789	3836	7625
Male	3161	3114	6275

## End points

### End points reporting groups

Reporting group title	Zoster-022 GSK1437173A Group
Reporting group description: Subjects receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Reporting group title	Zoster-022 Placebo Group
Reporting group description: Subjects receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022 GSK1437173A 70-79YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects between 70 and 79 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022 GSK1437173A >=80YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects above 80 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022 GSK1437173A >=70YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects above 70 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022 Placebo 70-79YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects between 70 and 79 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022 Placebo >=80YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects above 80 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022 Placebo >=70YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects above 70 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022/006 Pooled GSK1437173A 70-79YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects between 70 and 79 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022/006 Pooled GSK1437173A >=80YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects above 80 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.	
Subject analysis set title	Zoster-022/006 Pooled GSK1437173A >=70YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects above 70 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo 70-79YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 70 and 79 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo >=80YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects above 80 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo >=70YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects above 70 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled GSK1437173A 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 50 and 59 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled GSK1437173A 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 60 and 69 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled GSK1437173A 70-79 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 70 and 79 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled GSK1437173A >=80 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects above 80 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo 50-59 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 50 and 59 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo 60-69 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 60 and 69 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo 70-79 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects between 70 and 79 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo >=80 YOA Group
Subject analysis set type	Sub-group analysis



Subject analysis set description:

Subjects above 80 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled GSK1437173A >=70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects above 70 years of age (YOA), receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Subject analysis set title	Zoster-022/006 Pooled Placebo >=70 YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects above 70 years of age (YOA), receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

### Primary: Number of subjects with any episodes of herpes zoster (HZ)

End point title	Number of subjects with any episodes of herpes zoster (HZ)
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End point description:

Confirmed HZ cases during the study in the modified total vaccinated cohort (mTVc).

End point type	Primary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A >=80YOA Group	Zoster-022 GSK1437173A >=70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5114	1427	6541	5189
Units: Subjects	17	6	23	169

End point values	Zoster-022 Placebo >=80YOA Group	Zoster-022 Placebo >=70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1433	6622		
Units: Subjects	54	223		

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Zoster-022 Placebo 70-79YOA Group v Zoster-022 GSK1437173A 70-79YOA Group

Number of subjects included in analysis	10303
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Poisson
Parameter estimate	1-RR
Point estimate	90.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	83.54
upper limit	94.32

<b>Statistical analysis title</b>	Statistical analysis 2
Comparison groups	Zoster-022 Placebo $\geq$ 80YOA Group v Zoster-022 GSK1437173A $\geq$ 80YOA Group
Number of subjects included in analysis	2860
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Poisson
Parameter estimate	1-RR
Point estimate	89.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	74.65
upper limit	96.16

<b>Statistical analysis title</b>	Statistical analysis 3
Comparison groups	Zoster-022 GSK1437173A $\geq$ 70YOA Group v Zoster-022 Placebo $\geq$ 70YOA Group
Number of subjects included in analysis	13163
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Poisson
Parameter estimate	1-RR
Point estimate	89.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	84.29
upper limit	93.66

**Primary: Outcome measure for the pooled analysis of combined data from studies ZOSTER-006 (NCT01165177) and ZOSTER-022 (NCT01165229): Number of subjects with post-herpetic neuralgia (PHN)**

End point title	Outcome measure for the pooled analysis of combined data from studies ZOSTER-006 (NCT01165177) and ZOSTER-022 (NCT01165229): Number of subjects with post-herpetic neuralgia (PHN)
End point description: Incidence of PHN calculated using the mTVc during the entire study period in subjects $\geq 70$ years of age (YOA).	
End point type	Primary
End point timeframe: During the entire study period (3 to 5 year period following Day 0)	

End point values	Zoster-022/006 Pooled GSK1437173A 70-79YOA Group	Zoster-022/006 Pooled GSK1437173A $\geq 80$ YOA Group	Zoster-022/006 Pooled GSK1437173A $\geq 70$ YOA Group	Zoster-022/006 Pooled Placebo 70-79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6468	1782	8250	6554
Units: Subjects	2	2	4	29

End point values	Zoster-022/006 Pooled Placebo $\geq 80$ YOA Group	Zoster-022/006 Pooled Placebo $\geq 70$ YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1792	8346		
Units: Subjects	7	36		

**Statistical analyses**

<b>Statistical analysis title</b>	Statistical analysis 1
Comparison groups	Zoster-022/006 Pooled GSK1437173A 70-79YOA Group v Zoster-022/006 Pooled Placebo 70-79YOA Group
Number of subjects included in analysis	13022
Analysis specification	Pre-specified
Analysis type	
P-value	$< 0.0001$
Method	Poisson
Parameter estimate	1-RR
Point estimate	93.04

Confidence interval	
level	95 %
sides	2-sided
lower limit	72.47
upper limit	99.19

<b>Statistical analysis title</b>	Statistical analysis 2
Comparison groups	Zoster-022/006 Pooled GSK1437173A $\geq$ 80YOA Group v Zoster-022/006 Pooled Placebo $\geq$ 80YOA Group
Number of subjects included in analysis	3574
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1844
Method	Poisson
Parameter estimate	1-RR
Point estimate	71.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-51.51
upper limit	97.08

<b>Statistical analysis title</b>	Statistical analysis 3
Comparison groups	Zoster-022/006 Pooled GSK1437173A $\geq$ 70YOA Group v Zoster-022/006 Pooled Placebo $\geq$ 70YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Poisson
Parameter estimate	1-RR
Point estimate	88.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.7
upper limit	97.1

**Primary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with confirmed HZ**

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with confirmed HZ
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End point description:

Occurrence of confirmed HZ during the entire study period in subjects  $\geq 70$  YOA.

End point type	Primary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022/006 Pooled GSK1437173A 70-79YOA Group	Zoster-022/006 Pooled GSK1437173A $\geq 80$ YOA Group	Zoster-022/006 Pooled GSK1437173A $\geq 70$ YOA Group	Zoster-022/006 Pooled Placebo 70-79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6468	1782	8250	6554
Units: Subjects	19	6	25	216

End point values	Zoster-022/006 Pooled Placebo $\geq 80$ YOA Group	Zoster-022/006 Pooled Placebo $\geq 70$ YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1792	8346		
Units: Subjects	68	284		

## Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Zoster-022/006 Pooled GSK1437173A 70-79YOA Group v Zoster-022/006 Pooled Placebo 70-79YOA Group
Number of subjects included in analysis	13022
Analysis specification	Pre-specified
Analysis type	
P-value	$< 0.0001$
Method	Poisson
Parameter estimate	1-RR
Point estimate	91.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	86.04
upper limit	94.85

Statistical analysis title	Statistical analysis 2
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Comparison groups	Zoster-022/006 Pooled GSK1437173A $\geq$ 80YOA Group v Zoster-022/006 Pooled Placebo $\geq$ 80YOA Group
Number of subjects included in analysis	3574
Analysis specification	Pre-specified
Analysis type	
P-value	$< 0.0001$
Method	Poisson
Parameter estimate	1-RR
Point estimate	91.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	80.22
upper limit	96.94

<b>Statistical analysis title</b>	Statistical analysis 3
Comparison groups	Zoster-022/006 Pooled Placebo $\geq$ 70YOA Group v Zoster-022/006 Pooled GSK1437173A $\geq$ 70YOA Group
Number of subjects included in analysis	16596
Analysis specification	Pre-specified
Analysis type	
P-value	$< 0.0001$
Method	Poisson
Parameter estimate	1-RR
Point estimate	91.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	86.88
upper limit	94.46

### Secondary: Number of subjects with post-herpetic neuralgia (PHN)

End point title	Number of subjects with post-herpetic neuralgia (PHN)
End point description: PHN cases in the mTVc.	
End point type	Secondary
End point timeframe: During the entire study period (3 to 5 year period following Day 0)	

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A >=80YOA Group	Zoster-022 GSK1437173A >=70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5114	1427	6541	5189
Units: Subjects	2	2	4	22

End point values	Zoster-022 Placebo >=80YOA Group	Zoster-022 Placebo >=70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1433	6622		
Units: Subjects	6	28		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of days with severe 'worst' HZ-associated pain

End point title	Number of days with severe 'worst' HZ-associated pain
End point description:	
Duration of severe 'worst' HZ-associated pain following the onset of a confirmed HZ rash over the entire pain reporting period as measured by the Zoster Brief Pain Inventory (ZBPI) in subjects with confirmed HZ.	
End point type	Secondary
End point timeframe:	
During the entire study period (3 to 5 year period following Day 0)	

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A >=80YOA Group	Zoster-022 GSK1437173A >=70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	15	3	18	150
Units: Days				
arithmetic mean (standard deviation)	21.8 (± 31.41)	98.7 (± 57.73)	34.6 (± 45.54)	47.9 (± 100.08)

End point values	Zoster-022 Placebo >=80YOA Group	Zoster-022 Placebo >=70YOA Group		
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Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	48	198		
Units: Days				
arithmetic mean (standard deviation)	50.4 (± 106.51)	48.5 (± 101.4)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with confirmed HZ episode related mortality and hospitalizations

End point title	Number of subjects with confirmed HZ episode related mortality and hospitalizations
End point description:	
End point type	Secondary
End point timeframe:	
During the entire study period (3 to 5 year period following Day 0)	

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A ≥80YOA Group	Zoster-022 GSK1437173A ≥70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5114	1427	6541	5189
Units: Subjects				
Mortality	0	0	0	0
Hospitalization	0	0	0	3
Mortality or hospitalization	0	0	0	3

End point values	Zoster-022 Placebo ≥80YOA Group	Zoster-022 Placebo ≥70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1433	6622		
Units: Subjects				
Mortality	0	0		
Hospitalization	2	5		
Mortality or hospitalization	2	5		

## Statistical analyses



No statistical analyses for this end point

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**Secondary: Number of subjects with overall mortality and HZ-related mortality**

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End point title	Number of subjects with overall mortality and HZ-related mortality
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End point description:

Incidence of overall and HZ-related mortality during the study.

End point type	Secondary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

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End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A >=80YOA Group	Zoster-022 GSK1437173A >=70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5114	1427	6541	5189
Units: Subjects	0	0	0	0

End point values	Zoster-022 Placebo >=80YOA Group	Zoster-022 Placebo >=70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1433	6622		
Units: Subjects	0	0		

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Number of subjects with confirmed HZ episode related hospitalizations**

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End point title	Number of subjects with confirmed HZ episode related hospitalizations
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End point description:

Incidence of overall and HZ-related hospitalizations during the study.

End point type	Secondary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

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End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A >=80YOA Group	Zoster-022 GSK1437173A >=70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5114	1427	6541	5189
Units: Subjects	0	0	0	3

End point values	Zoster-022 Placebo >=80YOA Group	Zoster-022 Placebo >=70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1433	6622		
Units: Subjects	2	5		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with HZ related complications

End point title	Number of subjects with HZ related complications
End point description: Incidence of HZ complications during the study in subjects with confirmed HZ.	
End point type	Secondary
End point timeframe: During the entire study period (3 to 5 year period following Day 0)	

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A >=80YOA Group	Zoster-022 GSK1437173A >=70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	6	23	169
Units: Subjects				
At least one complication	1	0	1	6
HZ vasculitis	0	0	0	0
Disseminated Disease	0	0	0	0
Ophthalmic Disease	1	0	1	4
Neurologic Disease	0	0	0	3
Visceral Disease	0	0	0	0
Stroke	0	0	0	0

End point values	Zoster-022 Placebo ≥80YOA Group	Zoster-022 Placebo ≥70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54	223		
Units: Subjects				
At least one complication	4	10		
HZ vasculitis	0	0		
Disseminated Disease	2	2		
Ophthalmic Disease	2	6		
Neurologic Disease	0	3		
Visceral Disease	0	0		
Stroke	0	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects receiving pain medication associated with HZ

End point title	Number of subjects receiving pain medication associated with HZ
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End point description:

End point type	Secondary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A ≥80YOA Group	Zoster-022 GSK1437173A ≥70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	17	6	23	169
Units: Subjects				
At least 1 pain medication	7	3	10	123
1 pain medication only	5	0	5	43
2 pain medications only	0	1	1	30
3 pain medications or more	2	2	4	50

End point values	Zoster-022 Placebo ≥80YOA Group	Zoster-022 Placebo ≥70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	54	223		
Units: Subjects				

At least 1 pain medication	37	160		
1 pain medication only	17	60		
2 pain medications only	4	34		
3 pain medications or more	16	66		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of days with pain medication associated with HZ

End point title	Number of days with pain medication associated with HZ
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End point description:

End point type	Secondary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022 GSK1437173A 70-79YOA Group	Zoster-022 GSK1437173A ≥80YOA Group	Zoster-022 GSK1437173A ≥70YOA Group	Zoster-022 Placebo 70- 79YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7	3	10	123
Units: Days				
arithmetic mean (standard deviation)	38.7 (± 56.44)	274.7 (± 337)	109.5 (± 200.88)	218.6 (± 593.8)

End point values	Zoster-022 Placebo ≥80YOA Group	Zoster-022 Placebo ≥70YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	37	160		
Units: Days				
arithmetic mean (standard deviation)	135 (± 207.31)	199.3 (± 530.6)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with solicited local symptoms

End point title	Number of subjects with solicited local symptoms
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End point description:

Occurrence, intensity of each solicited local symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset; Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site. Relationship analysis was not performed.

End point type	Secondary
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End point timeframe:

Within the 7 days (Days 0-6) after each vaccination

End point values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	505	505		
Units: Subjects				
Any Pain, Dose 1 (N=502;504)	297	26		
Grade 3 Pain, Dose 1 (N=502;504)	12	1		
Any Redness, Dose 1 (N=502;504)	143	3		
Grade 3 Redness, Dose 1 (N=502;504)	9	0		
Any Swelling, Dose 1 (N=502;504)	85	2		
Grade 3 Swelling, Dose 1 (N=502;504)	2	0		
Any Pain, Dose 2 (N=492;491)	282	23		
Grade 3 Pain, Dose 2 (N=492;491)	12	0		
Any Redness, Dose 2 (N=492;491)	137	3		
Grade 3 Redness, Dose 2 (N=492;491)	15	0		
Any Swelling, Dose 2 (N=492;491)	68	0		
Grade 3 Swelling, Dose 2 (N=492;491)	7	0		
Any Pain, Across Doses (N=505;505)	347	43		
Grade 3 Pain, Across Doses (N=505;505)	22	1		
Any Redness, Across Doses (N=505;505)	198	5		
Grade 3 Redness, Across Doses (N=505;505)	20	0		
Any Swelling, Across Doses (N=505;505)	114	2		
Grade 3 Swelling, Across Doses (N=505;505)	8	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with solicited general symptoms

End point title	Number of subjects with solicited general symptoms
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End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal symptoms, headache, myalgia, shivering and fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that

prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
End point timeframe:	
Within the 7 days (Days 0-6) post-vaccination period	

End point values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	501	505		
Units: Subjects				
Any Fatigue, Dose 1 (N=501;503)	104	56		
Grade 3 Fatigue, Dose 1 (N=501;503)	8	4		
Related Fatigue, Dose 1 (N=501;503)	85	34		
Any Gastrointestinal, Dose 1 (N=501;503)	25	28		
Grade 3 Gastrointestinal, Dose 1 (N=501;503)	3	2		
Related Gastrointestinal, Dose 1 (N=501;503)	16	14		
Any Headache, Dose 1 (N=501;503)	72	42		
Grade 3 Headache, Dose 1 (N=501;503)	2	4		
Related Headache, Dose 1 (N=501;503)	58	27		
Any Myalgia, Dose 1 (N=501;503)	106	27		
Grade 3 Myalgia, Dose 1 (N=501;503)	6	2		
Related Myalgia, Dose 1 (N=501;503)	91	16		
Any Shivering, Dose 1 (N=501;503)	38	17		
Grade 3 Shivering, Dose 1 (N=501;503)	1	1		
Related Shivering, Dose 1 (N=501;503)	32	12		
Any Temperature, Dose 1 (N=501;503)	39	9		
Grade 3 Temperature, Dose 1 (N=501;503)	0	2		
Related Temperature, Dose 1 (N=501;503)	31	4		
Any Fatigue, Dose 2 (N=492;489)	122	39		
Grade 3 Fatigue, Dose 2 (N=492;489)	9	0		
Related Fatigue, Dose 2 (N=492;489)	105	30		
Any Gastrointestinal, Dose 2 (N=492;489)	37	19		
Grade 3 Gastrointestinal, Dose 2 (N=492;489)	3	1		
Related Gastrointestinal, Dose 2 (N=492;489)	26	13		
Any Headache, Dose 2 (N=492;489)	76	26		
Grade 3 Headache, Dose 2 (N=492;489)	4	0		
Related Headache, Dose 2 (N=492;489)	63	20		
Any Myalgia, Dose 2 (N=492;489)	113	18		
Grade 3 Myalgia, Dose 2 (N=492;489)	7	0		
Related Myalgia, Dose 2 (N=492;489)	94	16		
Any Shivering, Dose 2 (N=492;489)	59	11		

Grade 3 Shivering, Dose 2 (N=492;489)	5	1		
Related Shivering, Dose 2 (N=492;489)	47	9		
Any Temperature, Dose 2 (N=492;489)	38	6		
Grade 3 Temperature, Dose 2 (N=492;489)	0	2		
Related Temperature, Dose 2 (N=492;489)	35	2		
Any Fatigue, Across Doses (N=504;505)	166	77		
Grade 3 Fatigue, Across Doses (N=504;505)	16	4		
Related Fatigue, Across Doses (N=504;505)	140	52		
Any Gastrointestinal, Across Doses (N=504;505)	55	40		
Grade 3 Gastrointestinal, Across Doses (N=504;505)	5	2		
Related Gastrointestinal, Across Doses (N=504;505)	38	21		
Any Headache, Across Doses (N=504;505)	124	55		
Grade 3 Headache, Across Doses (N=504;505)	5	4		
Related Headache, Across Doses (N=504;505)	104	37		
Any Myalgia, Across Doses (N=504;505)	157	41		
Grade 3 Myalgia, Across Doses (N=504;505)	12	2		
Related Myalgia, Across Doses (N=504;505)	137	29		
Any Shivering, Across Doses (N=504;505)	75	22		
Grade 3 Shivering, Across Doses (N=504;505)	6	2		
Related Shivering, Across Doses (N=504;505)	64	16		
Any Temperature, Across Doses (N=504;505)	62	13		
Grade 3 Temperature, Across Doses (N=504;505)	0	2		
Related Temperature, Across Doses (N=504;505)	54	6		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)
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End point description:

Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0-29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects. An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as

related to the vaccination.

End point type	Secondary
End point timeframe:	
Within the 30 days (Days 0-29) after each vaccination	

End point values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6950	6950		
Units: Subjects				
Any AE(s)	3859	2263		
Grade 3 AE(s)	485	265		
Related AE(s)	2853	529		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with any, related and fatal serious adverse events (SAEs)

End point title	Number of subjects with any, related and fatal serious adverse events (SAEs)
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End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary
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End point timeframe:

From Month 0 to Month 14 and until study end (3 to 5 year period following Day 0)

End point values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6950	6695		
Units: Subjects				
Any SAE(s) up to Month 14	891	939		
Related SAE(s) up to Month 14	12	7		
Fatal SAE(s) up to Month 14	101	110		
Any SAE(s) up to study end	1153	1214		
Related SAE(s) up to study end	12	8		
Fatal SAE(s) up to study end	426	459		



## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with potential immune mediated diseases (pIMDs)

End point title	Number of subjects with potential immune mediated diseases (pIMDs)
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End point description:

Occurrence and relationship to vaccination of any potential immune-mediated diseases (pIMDs) during the entire study period in all subjects

End point type	Secondary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6950	6950		
Units: Subjects	92	97		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with Medically Attended events (MAEs)

End point title	Number of subjects with Medically Attended events (MAEs)
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End point description:

Occurrence and relationship to vaccination of medically attended visits other than routine health care visits, from Month 0 to Month 8 in all subjects. MAEs were defined as events for which the subject received medical attention defined as hospitalization, an emergency room visit, or a visit to or from medical personnel (medical doctor) for any reason. Any MAE(s) = Occurrence of any MAE(s) regardless of intensity grade or relation to vaccination.

End point type	Secondary
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End point timeframe:

From Month 0 to Month 8 post-vaccination

End point values	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6950	6950		
Units: Subjects				
Any MAE(s)	2882	2911		
Related MAE(s)	165	66		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Overall number of subjects with PHN in subjects $\geq$ 50 YOA

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Overall number of subjects with PHN in subjects $\geq$ 50 YOA
End point description:	Incidence of PHN calculated using the mTVc during the entire study period in subjects $\geq$ 50 YOA.
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022/006 Pooled GSK1437173A 50-59 YOA Group	Zoster-022/006 Pooled GSK1437173A 60-69 YOA Group	Zoster-022/006 Pooled GSK1437173A 70-79 YOA Group	Zoster-022/006 Pooled GSK1437173A $\geq$ 80 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3491	2140	6468	1782
Units: Subjects	0	0	2	2

End point values	Zoster-022/006 Pooled Placebo 50-59 YOA Group	Zoster-022/006 Pooled Placebo 60-69 YOA Group	Zoster-022/006 Pooled Placebo 70-79 YOA Group	Zoster-022/006 Pooled Placebo $\geq$ 80 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3523	2166	6554	1792
Units: Subjects	8	2	29	7

## Statistical analyses

No statistical analyses for this end point

### Secondary: Outcome measure for the pooled analysis of combined data from studies

**Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with a reduction of PHN incidence in subjects  $\geq$  50 YOA with confirmed HZ**

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with a reduction of PHN incidence in subjects $\geq$ 50 YOA with confirmed HZ
End point description: Occurrence of PHN during the entire study period in all subjects with confirmed HZ.	
End point type	Secondary
End point timeframe: During the entire study period (3 to 5 year period following Day 0)	

End point values	Zoster-022/006 Pooled GSK1437173A 50-59 YOA Group	Zoster-022/006 Pooled GSK1437173A 60-69 YOA Group	Zoster-022/006 Pooled GSK1437173A 70-79 YOA Group	Zoster-022/006 Pooled GSK1437173A $\geq$ 80 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	19	6
Units: Subjects	0	0	2	2

End point values	Zoster-022/006 Pooled Placebo 50-59 YOA Group	Zoster-022/006 Pooled Placebo 60-69 YOA Group	Zoster-022/006 Pooled Placebo 70-79 YOA Group	Zoster-022/006 Pooled Placebo $\geq$ 80 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	103	90	216	68
Units: Subjects	8	2	29	7

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with reduction of duration of severe 'worst' HZ-associated pain in subjects  $\geq$  70 YOA with confirmed HZ.**

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with reduction of duration of severe 'worst' HZ-associated pain in subjects $\geq$ 70 YOA with confirmed HZ.
End point description: Number of subjects with reduction of duration of severe 'worst' HZ-associated pain following the onset of a confirmed HZ rash over the entire pain reporting period as measured by the ZBPI in subjects $\geq$ 70 YOA with confirmed HZ.	
End point type	Secondary

End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022/006 Pooled GSK1437173A 70-79 YOA Group	Zoster-022/006 Pooled GSK1437173A ≥80 YOA Group	Zoster-022/006 Pooled Placebo 70-79 YOA Group	Zoster-022/006 Pooled Placebo ≥80 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	6	216	68
Units: Subjects	17	3	193	61

End point values	Zoster-022/006 Pooled GSK1437173A ≥70 YOA Group	Zoster-022/006 Pooled Placebo ≥70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	25	284		
Units: Subjects	20	254		

### Statistical analyses

No statistical analyses for this end point

**Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of days with severe 'worst' HZ-associated pain in subjects ≥ 70 YOA with confirmed HZ.**

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of days with severe 'worst' HZ-associated pain in subjects ≥ 70 YOA with confirmed HZ.
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End point description:

Reduction of duration of severe 'worst' HZ-associated pain following the onset of a confirmed HZ rash over the entire pain reporting period as measured by the ZBPI in subjects ≥ 70 YOA with confirmed HZ.

End point type	Secondary
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End point timeframe:

During the entire study period (3 to 5 year period following Day 0)

End point values	Zoster-022/006 Pooled GSK1437173A 70-79 YOA Group	Zoster-022/006 Pooled GSK1437173A ≥80 YOA Group	Zoster-022/006 Pooled Placebo 70-79 YOA Group	Zoster-022/006 Pooled Placebo ≥80 YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	6	216	68
Units: Days				
number (not applicable)	347	299	9338	2764

End point values	Zoster-022/006 Pooled GSK1437173A ≥70 YOA Group	Zoster-022/006 Pooled Placebo ≥70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	25	284		
Units: Days				
number (not applicable)	646	12102		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any and Grade 3 solicited local symptoms

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any and Grade 3 solicited local symptoms
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End point description:

Occurrence, intensity of each solicited local symptom within 7 days (Days 0-6) after each vaccination, in subjects ≥ 70 YOA. Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimeters (mm) of injection site. Relationship analysis was not performed..

End point type	Secondary
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End point timeframe:

Within 7 days (Days 0-6) after each vaccination

End point values	Zoster-022/006 Pooled GSK1437173A ≥70 YOA Group	Zoster-022/006 Pooled Placebo ≥70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2258	2263		
Units: Subjects				
Any Pain, Dose 1 (N=2246;2255)	1336	128		
Grade 3 Pain, Dose 1 (N=2246;2255)	42	1		
Any Redness, Dose 1 (N=2246;2255)	606	17		
Grade 3 Redness, Dose 1 (N=2246;2255)	43	0		
Any Swelling, Dose 1 (N=2246;2255)	455	17		
Grade 3 Swelling, Dose 1 (N=2246;2255)	17	0		
Any Pain, Dose 2 (N=2160;2169)	1241	107		
Grade 3 Pain, Dose 2 (N=2160;2169)	60	3		
Any Redness, Dose 2 (N=2160;2169)	582	14		
Grade 3 Redness, Dose 2 (N=2160;2169)	39	0		
Any Swelling, Dose 2 (N=2160;2169)	344	10		
Grade 3 Swelling, Dose 2 (N=2160;2169)	15	0		
Any Pain, Across Doses (N=2258;2263)	1562	199		
Grade 3 Pain, Across Doses (N=2258;2263)	290	4		
Any Redness, Across Doses (N=2258;2263)	851	27		
Grade 3 Redness, Across Doses (N=2258;2263)	70	0		
Any Swelling, Across Doses (N=2258;2263)	519	25		
Grade 3 Swelling, Across Doses (N=2258;2263)	30	0		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any, Grade 3 and related solicited general symptoms

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any, Grade 3 and related solicited general symptoms
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### End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal symptoms, headache, myalgia, shivering and fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
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End point timeframe:

Within 7 days (Days 0-6) after each vaccination

<b>End point values</b>	Zoster-022/006 Pooled GSK1437173A >=70 YOA Group	Zoster-022/006 Pooled Placebo >=70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2252	2264		
Units: Subjects				
Any Fatigue, Dose 1 (N=2237;2256)	545	231		
Grade 3 Fatigue, Dose 1 (N=2237;2256)	31	13		
Related Fatigue, Dose 1 (N=2237;2256)	441	147		
Any Gastrointestinal, Dose 1 (N=2237;2256)	170	123		
Grade 3 Gastrointestinal, Dose 1 (N=2237;2256)	15	6		
Related Gastrointestinal, Dose 1 (N=2237;2256)	101	67		
Any Headache, Dose 1 (N=2237;2256)	380	189		
Grade 3 Headache, Dose 1 (N=2237;2256)	7	8		
Related Headache, Dose 1 (N=2237;2256)	293	132		
Any Myalgia, Dose 1 (N=2237;2256)	530	159		
Grade 3 Myalgia, Dose 1 (N=2237;2256)	26	7		
Related Myalgia, Dose 1 (N=2237;2256)	445	101		
Any Shivering, Dose 1 (N=2237;2256)	206	73		
Grade 3 Shivering, Dose 1 (N=2237;2256)	15	3		
Related Shivering, Dose 1 (N=2237;2256)	173	50		
Any Temperature, Dose 1 (N=2237;2256)	142	34		
Grade 3 Temperature, Dose 1 (N=2237;2256)	1	2		
Related Temperature, Dose 1 (N=2237;2256)	111	16		
Any Fatigue, Dose 2 (N=2159;2166)	579	169		
Grade 3 Fatigue, Dose 2 (N=2159;2166)	53	4		
Related Fatigue, Dose 2 (N=2159;2166)	495	116		
Any Gastrointestinal, Dose 2 (N=2159;2166)	188	75		
Grade 3 Gastrointestinal, Dose 2 (N=2159;2166)	14	5		
Related Gastrointestinal, Dose 2 (N=2159;2166)	142	35		
Any Headache, Dose 2 (N=2159;2166)	455	133		
Grade 3 Headache, Dose 2 (N=2159;2166)	30	2		

Related Headache, Dose 2 (N=2159;2166)	386	86		
Any Myalgia, Dose 2 (N=2159;2166)	560	112		
Grade 3 Myalgia, Dose 2 (N=2159;2166)	42	4		
Related Myalgia, Dose 2 (N=2159;2166)	484	75		
Any Shivering, Dose 2 (N=2159;2166)	334	55		
Grade 3 Shivering, Dose 2 (N=2159;2166)	36	4		
Related Shivering, Dose 2 (N=2159;2166)	292	34		
Any Temperature, Dose 2 (N=2159;2166)	224	30		
Grade 3 Temperature, Dose 2 (N=2159;2166)	2	3		
Related Temperature, Dose 2 (N=2159;2166)	189	14		
Any Fatigue, Across Doses (N=2252;2264)	825	326		
Grade 3 Fatigue, Across Doses (N=2252;2264)	79	17		
Related Fatigue, Across Doses (N=2252;2264)	699	220		
Any Gastrointestinal, Across Doses (N=2252;2264)	304	172		
Grade 3 Gastrointestinal, Across Doses(N=2252;2264)	26	10		
Related Gastrointestinal, Across Doses(N=2252;2264)	210	91		
Any Headache, Across Doses (N=2252;2264)	653	268		
Grade 3 Headache, Across Doses (N=2252;2264)	34	10		
Related Headache, Across Doses (N=2252;2264)	547	185		
Any Myalgia, Across Doses (N=2252;2264)	790	225		
Grade 3 Myalgia, Across Doses (N=2252;2264)	62	10		
Related Myalgia, Across Doses (N=2252;2264)	689	157		
Any Shivering, Across Doses (N=2252;2264)	439	110		
Grade 3 Shivering, Across Doses (N=2252;2264)	49	6		
Related Shivering, Across Doses (N=2252;2264)	380	75		
Any Temperature, Across Doses (N=2252;2264)	323	61		
Grade 3 Temperature, Across Doses (N=2252;2264)	3	3		
Related Temperature, Across Doses (N=2252;2264)	265	30		

## Statistical analyses

No statistical analyses for this end point



**Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with unsolicited AEs in subjects  $\geq$  70 YOA**

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with unsolicited AEs in subjects $\geq$ 70 YOA
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End point description:

Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0-29) after each vaccination, according to the MedDRA classification, in subjects  $\geq$  70 YOA. An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary
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End point timeframe:

Within 30 days (Days 0 - 29) after each vaccination

End point values	Zoster-022/006 Pooled GSK1437173A $\geq$ 70 YOA Group	Zoster-022/006 Pooled Placebo $\geq$ 70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8758	8773		
Units: Subjects				
Any AE(s)	4366	2732		
Grade 3 AE(s)	553	335		
Related AE(s)	2961	578		

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any, related and fatal SAEs**

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any, related and fatal SAEs
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End point description:

Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in subjects  $\geq$  70 YOA.

End point type	Secondary
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End point timeframe:

From Month 0 to Month 14 and until study end (3 to 5 year period following Day 0)

<b>End point values</b>	Zoster-022/006 Pooled GSK1437173A >=70 YOA Group	Zoster-022/006 Pooled Placebo >=70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8758	8773		
Units: Subjects				
Any SAEs up to Month 14	1117	1171		
Related SAEs up to Month 14	12	7		
Fatal SAEs up to Month 14	128	144		
Any SAEs up to study end	1447	1521		
Related SAEs up to study end	12	8		
Fatal SAEs up to study end	539	580		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any pIMDs

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with any pIMDs
End point description:	Occurrence and relationship to vaccination of any pIMDs during the entire study period in subjects ≥ 70 YOA.
End point type	Secondary
End point timeframe:	During the entire study period (3 to 5 year period following Day 0)

<b>End point values</b>	Zoster-022/006 Pooled GSK1437173A >=70 YOA Group	Zoster-022/006 Pooled Placebo >=70 YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8758	8773		
Units: Subjects				
Any pIMD(s)	110	118		
Related pIMD(s)	8	8		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with Medically Attended events (MAEs)

End point title	Outcome measure for the pooled analysis of combined data from studies Zoster-006 (NCT01165177) and Zoster-022 (NCT01165229): Number of subjects with Medically Attended events (MAEs)
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#### End point description:

Occurrence and relationship to vaccination of medically attended visits (defined as hospitalizations, emergency room visits or visits to or from medical personnel), other than routine health care visits, from Month 0 to Month 8 in subjects  $\geq 70$  YOA.

End point type	Secondary
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#### End point timeframe:

From Month 0 to Month 8 post-vaccination

End point values	Zoster-022/006 Pooled GSK1437173A $\geq 70$ YOA Group	Zoster-022/006 Pooled Placebo $\geq 70$ YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8758	8773		
Units: Subjects				
Any MAE(s)	3593	3648		
Related MAE(s)	180	80		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: within 7 days after vaccination; Unsolicited adverse events: within 30 days after vaccination; Serious adverse events: during the entire study period.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.0
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### Reporting groups

Reporting group title	Zoster-022 GSK1437173A Group
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Reporting group description:

Subjects receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Reporting group title	Zoster-022 Placebo Group
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Reporting group description:

Subjects receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

Reporting group title	Zoster-022/006 Pooled GSK1437173A Group
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Reporting group description:

Subjects receiving herpes zoster subunit vaccine (gE/AS01B vaccine) according to a 0, 2-month schedule.

Reporting group title	Zoster-022/006 Pooled Placebo Group
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Reporting group description:

Subjects receiving saline solution (NaCl solution) as control according to a 0, 2-month schedule.

<b>Serious adverse events</b>	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group	Zoster-022/006 Pooled GSK1437173A Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1153 / 6950 (16.59%)	1214 / 6950 (17.47%)	1447 / 8758 (16.52%)
number of deaths (all causes)	426	459	539
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acral lentiginous melanoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 monocytic leukaemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Acute myeloid leukaemia			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Acute promyelocytic leukaemia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	3 / 6950 (0.04%)	1 / 6950 (0.01%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Adenocarcinoma of colon			
subjects affected / exposed	4 / 6950 (0.06%)	4 / 6950 (0.06%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Adrenal adenoma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal gland cancer			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic astrocytoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Anaplastic thyroid cancer			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
B precursor type acute leukaemia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
B-cell lymphoma			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	5 / 6950 (0.07%)	3 / 6950 (0.04%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of orbit			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of thyroid gland			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumour			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign renal neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct adenocarcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Bladder cancer			
subjects affected / exposed	6 / 6950 (0.09%)	13 / 6950 (0.19%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Bladder cancer recurrent			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bladder papilloma			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Bone cancer			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Bowen's disease			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Brain cancer metastatic			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain neoplasm benign			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm malignant			



subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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			
subjects affected / exposed	5 / 6950 (0.07%)	4 / 6950 (0.06%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Breast cancer metastatic			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchial carcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Carcinoid tumour of the small bowel			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour pulmonary			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Central nervous system neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Cervix carcinoma recurrent			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			

subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 3
Cholesteatoma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Colon adenoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	9 / 6950 (0.13%)	6 / 6950 (0.09%)	11 / 8758 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 3	0 / 4	0 / 3
Colon cancer metastatic			
subjects affected / exposed	3 / 6950 (0.04%)	3 / 6950 (0.04%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 3
Colon neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Diffuse large B-cell lymphoma			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma stage IV			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Fallopian tube cancer			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular thyroid cancer			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Gastric cancer			
subjects affected / exposed	6 / 6950 (0.09%)	3 / 6950 (0.04%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 6
Gastrointestinal carcinoma			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Gastrointestinal stromal tumour			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Glioblastoma multiforme			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hepatic cancer			
subjects affected / exposed	2 / 6950 (0.03%)	6 / 6950 (0.09%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 5	0 / 4
Hepatic cancer metastatic			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Hepatic neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Hypergammaglobulinaemia benign monoclonal			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 adenocarcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive lobular breast carcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Invasive papillary breast carcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large cell lung cancer			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Large intestine benign neoplasm			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Laryngeal neoplasm			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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	1 / 6950 (0.01%)	6 / 6950 (0.09%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 1
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Lung adenocarcinoma stage III			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 cancer metastatic			
subjects affected / exposed	6 / 6950 (0.09%)	4 / 6950 (0.06%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 6	0 / 4	0 / 7
Lung neoplasm			

subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	22 / 6950 (0.32%)	13 / 6950 (0.19%)	27 / 8758 (0.31%)
occurrences causally related to treatment / all	0 / 22	0 / 13	0 / 27
deaths causally related to treatment / all	0 / 18	0 / 10	0 / 23
Lymphoma			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Malignant fibrous histiocytoma of bone			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Malignant lymphoma unclassifiable high grade			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 mast cell neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Malignant melanoma			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Malignant melanoma in situ			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater			

subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Malignant neoplasm of unknown primary site			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant palate neoplasm			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Mesothelioma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to adrenals			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastases to bone			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 2
Metastases to central nervous system			



subjects affected / exposed	4 / 6950 (0.06%)	2 / 6950 (0.03%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 4
Metastases to gastrointestinal tract			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Metastases to liver			
subjects affected / exposed	5 / 6950 (0.07%)	5 / 6950 (0.07%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 5	0 / 5
Metastases to lung			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastases to lymph nodes			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Metastases to pleura			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 stomach			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastasis			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Metastatic carcinoma of the bladder			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Metastatic gastric cancer			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Metastatic malignant melanoma			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 2
Metastatic neoplasm			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Myelodysplastic syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nasopharyngeal cancer			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 2
Neoplasm prostate			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Non-small cell lung cancer stage IV			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Oesophageal adenocarcinoma metastatic			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Oesophageal cancer metastatic			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Oesophageal carcinoma			
subjects affected / exposed	6 / 6950 (0.09%)	1 / 6950 (0.01%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 1	0 / 5
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Ovarian cancer			
subjects affected / exposed	4 / 6950 (0.06%)	0 / 6950 (0.00%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 6
Ovarian cancer recurrent			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Ovarian epithelial cancer			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian fibroma			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 germ cell teratoma benign			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	7 / 6950 (0.10%)	10 / 6950 (0.14%)	10 / 8758 (0.11%)
occurrences causally related to treatment / all	0 / 7	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 7	0 / 10	0 / 10
Pancreatic carcinoma metastatic			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 4
Pancreatic neoplasm			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Pancreatic neuroendocrine tumour			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraganglion neoplasm			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostate cancer			
subjects affected / exposed	19 / 6950 (0.27%)	18 / 6950 (0.26%)	22 / 8758 (0.25%)
occurrences causally related to treatment / all	0 / 19	0 / 18	0 / 22
deaths causally related to treatment / all	0 / 3	0 / 5	0 / 4
Prostate cancer metastatic			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 5
Prostate cancer recurrent			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Prostate cancer stage IV			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	4 / 6950 (0.06%)	1 / 6950 (0.01%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Rectal adenoma			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Rectal cancer recurrent			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal cancer metastatic			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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 cell carcinoma			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Renal cell carcinoma recurrent			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Sarcoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 cancer			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Small cell lung cancer metastatic			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Spinal cord neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sweat gland tumour			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell lymphoma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Testicular neoplasm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Thyroid cancer			

subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Transitional cell carcinoma			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma metastatic			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Urethral neoplasm			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval cancer			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm ruptured			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Angiodysplasia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 aneurysm			
subjects affected / exposed	6 / 6950 (0.09%)	2 / 6950 (0.03%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Aortic aneurysm rupture			
subjects affected / exposed	4 / 6950 (0.06%)	4 / 6950 (0.06%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 4
Aortic arteriosclerosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 dilatation			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 dissection			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Aortic occlusion			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Aortic rupture			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Aortic stenosis			
subjects affected / exposed	0 / 6950 (0.00%)	8 / 6950 (0.12%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arterial disorder			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arteriosclerosis			
subjects affected / exposed	1 / 6950 (0.01%)	5 / 6950 (0.07%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1
Arteriovenous fistula			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood pressure inadequately controlled			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	5 / 6950 (0.07%)	3 / 6950 (0.04%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 5
Deep vein thrombosis			

subjects affected / exposed	6 / 6950 (0.09%)	9 / 6950 (0.13%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Embolism			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Femoral artery aneurysm			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 6950 (0.01%)	6 / 6950 (0.09%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemodynamic instability			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Hypertension			
subjects affected / exposed	22 / 6950 (0.32%)	25 / 6950 (0.36%)	25 / 8758 (0.29%)
occurrences causally related to treatment / all	0 / 22	0 / 25	0 / 25
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Hypertensive crisis			

subjects affected / exposed	7 / 6950 (0.10%)	6 / 6950 (0.09%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	6 / 6950 (0.09%)	5 / 6950 (0.07%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Inferior vena caval occlusion			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Internal haemorrhage			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Labile hypertension			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microscopic polyangiitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrosis ischaemic			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypertension			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	6 / 6950 (0.09%)	6 / 6950 (0.09%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 ischaemia			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Superior vena cava syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thromboangiitis obliterans			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			



subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Venous thrombosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polypectomy			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Accidental death			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Administration site erythema			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Administration site pain			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adverse drug reaction			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Cardiac death			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Chest discomfort			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	20 / 6950 (0.29%)	19 / 6950 (0.27%)	24 / 8758 (0.27%)
occurrences causally related to treatment / all	0 / 20	0 / 19	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	17 / 6950 (0.24%)	29 / 6950 (0.42%)	20 / 8758 (0.23%)
occurrences causally related to treatment / all	0 / 17	0 / 29	0 / 20
deaths causally related to treatment / all	0 / 17	0 / 29	0 / 20
Device battery issue			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 deposit issue			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 dislocation			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 leakage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drowning			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Fatigue			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Generalised oedema			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ill-defined disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	9 / 6950 (0.13%)	12 / 6950 (0.17%)	12 / 8758 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 12	0 / 12
deaths causally related to treatment / all	0 / 9	0 / 11	0 / 12
Non-cardiac chest pain			
subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organ failure			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Pain			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 swelling			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Strangulated hernia			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 2
Sudden death			
subjects affected / exposed	13 / 6950 (0.19%)	4 / 6950 (0.06%)	16 / 8758 (0.18%)
occurrences causally related to treatment / all	0 / 13	0 / 4	0 / 16
deaths causally related to treatment / all	0 / 13	0 / 4	0 / 16
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Thrombosis in device			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergic granulomatous angiitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyloidosis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			

subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	9 / 6950 (0.13%)	7 / 6950 (0.10%)	10 / 8758 (0.11%)
occurrences causally related to treatment / all	0 / 9	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast dysplasia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Prostatitis			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal ulceration			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Acute respiratory failure			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 2
Aspiration			



subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Asthma			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchospasm			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 obstructive pulmonary disease			
subjects affected / exposed	21 / 6950 (0.30%)	18 / 6950 (0.26%)	27 / 8758 (0.31%)
occurrences causally related to treatment / all	0 / 21	0 / 18	0 / 27
deaths causally related to treatment / all	0 / 8	0 / 7	0 / 9
Diaphragmatic disorder			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Emphysema			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Epistaxis			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Lung disorder			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural calcification			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	5 / 6950 (0.07%)	8 / 6950 (0.12%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Pleurisy			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 aspiration			

subjects affected / exposed	10 / 6950 (0.14%)	3 / 6950 (0.04%)	11 / 8758 (0.13%)
occurrences causally related to treatment / all	0 / 10	0 / 3	0 / 11
deaths causally related to treatment / all	0 / 7	0 / 3	0 / 8
Pneumothorax			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Pulmonary cavitation			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
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 embolism			
subjects affected / exposed	15 / 6950 (0.22%)	21 / 6950 (0.30%)	19 / 8758 (0.22%)
occurrences causally related to treatment / all	0 / 15	0 / 21	0 / 19
deaths causally related to treatment / all	0 / 3	0 / 9	0 / 6
Pulmonary fibrosis			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 oedema			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Respiratory arrest			

subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Respiratory distress			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Respiratory failure			
subjects affected / exposed	15 / 6950 (0.22%)	15 / 6950 (0.22%)	20 / 8758 (0.23%)
occurrences causally related to treatment / all	0 / 15	0 / 15	0 / 20
deaths causally related to treatment / all	0 / 11	0 / 11	0 / 16
Sleep apnoea syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 psychosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Affective disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breathing-related sleep disorder			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
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	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Delirium febrile			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	4 / 6950 (0.06%)	3 / 6950 (0.04%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Major depression			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Mental disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder due to a general medical condition			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Panic attack			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective disorder bipolar type			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somatoform disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 glucose fluctuation			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			



subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate decreased			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight increased			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Accidental overdose			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm perforation			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ankle fracture			
subjects affected / exposed	3 / 6950 (0.04%)	5 / 6950 (0.07%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone fissure			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Cervical vertebral fracture			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Chemical poisoning			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
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 injury			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Comminuted fracture			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Compression fracture			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	4 / 6950 (0.06%)	3 / 6950 (0.04%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	4 / 6950 (0.06%)	5 / 6950 (0.07%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery reocclusion			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery restenosis			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Deep vein thrombosis postoperative			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye penetration			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Fall			
subjects affected / exposed	8 / 6950 (0.12%)	5 / 6950 (0.07%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Femoral neck fracture			
subjects affected / exposed	2 / 6950 (0.03%)	6 / 6950 (0.09%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Femur fracture			

subjects affected / exposed	10 / 6950 (0.14%)	15 / 6950 (0.22%)	15 / 8758 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			

subjects affected / exposed	5 / 6950 (0.07%)	4 / 6950 (0.06%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Hip fracture			
subjects affected / exposed	7 / 6950 (0.10%)	2 / 6950 (0.03%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Humerus fracture			
subjects affected / exposed	3 / 6950 (0.04%)	6 / 6950 (0.09%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Jaw fracture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney contusion			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ligament sprain			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Overdose			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Patella fracture			
subjects affected / exposed	3 / 6950 (0.04%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Post procedural haemorrhage			



subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pulmonary embolism			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 complication			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural intestinal perforation			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	5 / 6950 (0.07%)	5 / 6950 (0.07%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Rib fracture			

subjects affected / exposed	6 / 6950 (0.09%)	7 / 6950 (0.10%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin wound			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 4
Snake bite			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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	6 / 6950 (0.09%)	1 / 6950 (0.01%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 injury cervical			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal fracture			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	9 / 6950 (0.13%)	6 / 6950 (0.09%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 4
Subdural haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Synovial rupture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	4 / 6950 (0.06%)	4 / 6950 (0.06%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	4 / 6950 (0.06%)	2 / 6950 (0.03%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic fracture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Ulna fracture			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	4 / 6950 (0.06%)	4 / 6950 (0.06%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft occlusion			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound evisceration			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Wound haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Congenital, familial and genetic disorders			
Congenital cystic kidney disease			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pyloric stenosis			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal dysplasia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Acute left ventricular failure			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Acute myocardial infarction			
subjects affected / exposed	21 / 6950 (0.30%)	28 / 6950 (0.40%)	25 / 8758 (0.29%)
occurrences causally related to treatment / all	1 / 21	0 / 28	1 / 25
deaths causally related to treatment / all	0 / 10	0 / 14	0 / 10
Angina pectoris			
subjects affected / exposed	13 / 6950 (0.19%)	6 / 6950 (0.09%)	13 / 8758 (0.15%)
occurrences causally related to treatment / all	0 / 13	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	7 / 6950 (0.10%)	7 / 6950 (0.10%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Aortic valve incompetence			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 stenosis			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arrhythmia			
subjects affected / exposed	5 / 6950 (0.07%)	9 / 6950 (0.13%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 4
Arrhythmia supraventricular			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Atrial fibrillation			
subjects affected / exposed	40 / 6950 (0.58%)	54 / 6950 (0.78%)	49 / 8758 (0.56%)
occurrences causally related to treatment / all	0 / 40	0 / 54	0 / 49
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 7
Atrial flutter			
subjects affected / exposed	6 / 6950 (0.09%)	5 / 6950 (0.07%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			

subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	4 / 6950 (0.06%)	2 / 6950 (0.03%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block first degree			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
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	4 / 6950 (0.06%)	8 / 6950 (0.12%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	23 / 6950 (0.33%)	17 / 6950 (0.24%)	28 / 8758 (0.32%)
occurrences causally related to treatment / all	0 / 23	0 / 17	0 / 28
deaths causally related to treatment / all	0 / 22	0 / 17	0 / 27
Cardiac disorder			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			



subjects affected / exposed	51 / 6950 (0.73%)	57 / 6950 (0.82%)	64 / 8758 (0.73%)
occurrences causally related to treatment / all	0 / 51	0 / 57	0 / 64
deaths causally related to treatment / all	0 / 31	0 / 38	0 / 37
Cardiac failure acute			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 failure chronic			
subjects affected / exposed	3 / 6950 (0.04%)	6 / 6950 (0.09%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 3
Cardiac failure congestive			
subjects affected / exposed	23 / 6950 (0.33%)	33 / 6950 (0.47%)	31 / 8758 (0.35%)
occurrences causally related to treatment / all	0 / 23	0 / 33	0 / 31
deaths causally related to treatment / all	0 / 9	0 / 12	0 / 11
Cardiac tamponade			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac valve disease			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	3 / 6950 (0.04%)	5 / 6950 (0.07%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 3
Cardiogenic shock			
subjects affected / exposed	6 / 6950 (0.09%)	2 / 6950 (0.03%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomegaly			

subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Cardiomyopathy			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy alcoholic			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Cardiovascular deconditioning			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chronotropic incompetence			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cor pulmonale			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	28 / 6950 (0.40%)	25 / 6950 (0.36%)	32 / 8758 (0.37%)
occurrences causally related to treatment / all	0 / 28	0 / 25	0 / 32
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 5
Coronary artery insufficiency			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Coronary artery occlusion			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	3 / 6950 (0.04%)	6 / 6950 (0.09%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastolic dysfunction			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart valve incompetence			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Hypertensive heart disease			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Left ventricular failure			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Left ventricular hypertrophy			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Mitral valve incompetence			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve stenosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	41 / 6950 (0.59%)	45 / 6950 (0.65%)	59 / 8758 (0.67%)
occurrences causally related to treatment / all	0 / 41	0 / 45	0 / 59
deaths causally related to treatment / all	0 / 24	0 / 26	0 / 32
Myocardial ischaemia			
subjects affected / exposed	5 / 6950 (0.07%)	16 / 6950 (0.23%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 16	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 5	0 / 1
Palpitations			

subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pericarditis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Right ventricular failure			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Sinus arrest			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	5 / 6950 (0.07%)	6 / 6950 (0.09%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
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 tachycardia			

subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Tricuspid valve incompetence			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 2
Ventricular tachycardia			
subjects affected / exposed	2 / 6950 (0.03%)	6 / 6950 (0.09%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Amnesia			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Aphasia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balance disorder			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Basal ganglia haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Basal ganglia infarction			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 thrombosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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 infarction			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid sinus syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system lesion			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar haemorrhage			



subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Cerebellar ischaemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 artery embolism			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery thrombosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cerebral atrophy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	6 / 6950 (0.09%)	7 / 6950 (0.10%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 5	0 / 6	0 / 6
Cerebral infarction			
subjects affected / exposed	16 / 6950 (0.23%)	17 / 6950 (0.24%)	21 / 8758 (0.24%)
occurrences causally related to treatment / all	0 / 16	1 / 17	0 / 21
deaths causally related to treatment / all	0 / 5	0 / 6	0 / 9
Cerebral ischaemia			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 2
Cerebrospinal fluid leakage			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	34 / 6950 (0.49%)	31 / 6950 (0.45%)	45 / 8758 (0.51%)
occurrences causally related to treatment / all	0 / 34	1 / 31	0 / 45
deaths causally related to treatment / all	0 / 11	0 / 17	0 / 17
Cerebrovascular disorder			
subjects affected / exposed	3 / 6950 (0.04%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cervical myelopathy			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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			

subjects affected / exposed	4 / 6950 (0.06%)	2 / 6950 (0.03%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Dementia Alzheimer's type			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia with Lewy bodies			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 coma			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Dizziness			
subjects affected / exposed	1 / 6950 (0.01%)	5 / 6950 (0.07%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drop attacks			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dural arteriovenous fistula			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspraxia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Epilepsy			

subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Haemorrhagic stroke			
subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertonia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Ischaemic stroke			
subjects affected / exposed	7 / 6950 (0.10%)	6 / 6950 (0.09%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 4
Lacunar infarction			

subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Lumbar radiculopathy			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 encephalopathy			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Miller Fisher syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed dementia			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis cranial			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paralysis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Parkinson's disease			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 herpetic neuralgia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Progressive supranuclear palsy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Radiculopathy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless legs syndrome			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			



subjects affected / exposed	4 / 6950 (0.06%)	4 / 6950 (0.06%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Senile dementia			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Somnolence			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 claudication			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Subarachnoid haemorrhage			
subjects affected / exposed	5 / 6950 (0.07%)	7 / 6950 (0.10%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 5	0 / 2	0 / 5
Syncope			

subjects affected / exposed	11 / 6950 (0.16%)	20 / 6950 (0.29%)	15 / 8758 (0.17%)
occurrences causally related to treatment / all	0 / 11	1 / 20	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Thrombotic cerebral infarction			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Transient global amnesia			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	20 / 6950 (0.29%)	14 / 6950 (0.20%)	22 / 8758 (0.25%)
occurrences causally related to treatment / all	0 / 20	0 / 14	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal neuralgia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIIth nerve lesion			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			

subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 6950 (0.09%)	13 / 6950 (0.19%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Haemorrhagic anaemia			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersplenism			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	5 / 6950 (0.07%)	4 / 6950 (0.06%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic anaemia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pernicious anaemia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Ear and labyrinth disorders			
Sudden hearing loss			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			

subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amaurosis fugax			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	7 / 6950 (0.10%)	7 / 6950 (0.10%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choroidal effusion			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridocele			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iritis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens dislocation			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular hypertension			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular vascular disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic ischaemic neuropathy			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal degeneration			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			

subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Abdominal discomfort			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 6950 (0.01%)	7 / 6950 (0.10%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal strangulated hernia			



subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal prolapse			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Autoimmune pancreatitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Barrett's oesophagus			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	3 / 6950 (0.04%)	1 / 6950 (0.01%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia, obstructive			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diverticulum			
subjects affected / exposed	3 / 6950 (0.04%)	3 / 6950 (0.04%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Duodenal ulcer			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Duodenal ulcer perforation			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Enteritis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical fistula			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecal incontinence			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	4 / 6950 (0.06%)	6 / 6950 (0.09%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Gastric ulcer haemorrhage			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Gastritis			
subjects affected / exposed	3 / 6950 (0.04%)	6 / 6950 (0.09%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis alcoholic			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Haemorrhoids			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	6 / 6950 (0.09%)	7 / 6950 (0.10%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Inguinal hernia			
subjects affected / exposed	5 / 6950 (0.07%)	10 / 6950 (0.14%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal congestion			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal infarction			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Intestinal ischaemia			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Intestinal obstruction			
subjects affected / exposed	6 / 6950 (0.09%)	6 / 6950 (0.09%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1
Intestinal perforation			

subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Large intestinal obstruction			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Large intestine perforation			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Large intestine polyp			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery embolism			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Mesenteric artery thrombosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Mesenteritis			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophageal haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal spasm			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oesophageal ulcer haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic disorder			



subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	3 / 6950 (0.04%)	8 / 6950 (0.12%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pancreatitis acute			
subjects affected / exposed	5 / 6950 (0.07%)	4 / 6950 (0.06%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	1 / 5	0 / 4	1 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Peptic ulcer			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal perforation			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haemorrhage			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Salivary gland calculus			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	2 / 6950 (0.03%)	4 / 6950 (0.06%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Subileus			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis mesenteric vessel			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Umbilical hernia			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Volvulus			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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			
Acute hepatic failure			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Bile duct obstruction			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			

subjects affected / exposed	3 / 6950 (0.04%)	3 / 6950 (0.04%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 dyskinesia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	5 / 6950 (0.07%)	5 / 6950 (0.07%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cholangitis acute			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cholecystitis			
subjects affected / exposed	7 / 6950 (0.10%)	15 / 6950 (0.22%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cholecystitis acute			
subjects affected / exposed	7 / 6950 (0.10%)	4 / 6950 (0.06%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cholecystitis chronic			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	14 / 6950 (0.20%)	14 / 6950 (0.20%)	14 / 8758 (0.16%)
occurrences causally related to treatment / all	0 / 14	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cholestasis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Chronic hepatic failure			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Cirrhosis alcoholic			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Drug-induced liver injury			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Gallbladder perforation			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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 cirrhosis			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Hepatic failure			

subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Hepatic function abnormal			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 alcoholic			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hyperbilirubinaemia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic hepatitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Jaundice cholestatic			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Dermal cyst			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis contact			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatomyositis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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			
subjects affected / exposed	0 / 6950 (0.00%)	5 / 6950 (0.07%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Drug eruption			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			

subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoplakia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen planus			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 necrosis			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Skin ulcer			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stasis dermatitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			



subjects affected / exposed	18 / 6950 (0.26%)	19 / 6950 (0.27%)	23 / 8758 (0.26%)
occurrences causally related to treatment / all	0 / 18	0 / 19	0 / 23
deaths causally related to treatment / all	0 / 8	0 / 7	0 / 12
Acute prerenal failure			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neck obstruction			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder perforation			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Bladder prolapse			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Calculus ureteric			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	4 / 6950 (0.06%)	11 / 6950 (0.16%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cystitis interstitial			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 nephropathy			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Haematuria			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephroangiosclerosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	6 / 6950 (0.09%)	2 / 6950 (0.03%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy toxic			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic bladder			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Renal artery occlusion			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 cyst			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	11 / 6950 (0.16%)	11 / 6950 (0.16%)	11 / 8758 (0.13%)
occurrences causally related to treatment / all	0 / 11	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 7	0 / 3	0 / 7
Renal hypertension			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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 mass			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 6950 (0.00%)	4 / 6950 (0.06%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral haemorrhage			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Urethral meatus stenosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Urinary retention			

subjects affected / exposed	3 / 6950 (0.04%)	3 / 6950 (0.04%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract disorder			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cushingoid			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism primary			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopituitarism			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Acquired claw toe			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthrofibrosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 6950 (0.03%)	5 / 6950 (0.07%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			

subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrocalcinosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	5 / 6950 (0.07%)	4 / 6950 (0.06%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscal degeneration			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed connective tissue disease			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			



subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	26 / 6950 (0.37%)	17 / 6950 (0.24%)	30 / 8758 (0.34%)
occurrences causally related to treatment / all	0 / 26	0 / 17	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondritis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporosis			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Osteoporotic fracture			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	5 / 6950 (0.07%)	4 / 6950 (0.06%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	1 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyositis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Pseudarthrosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sjogren's syndrome			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			

subjects affected / exposed	6 / 6950 (0.09%)	6 / 6950 (0.09%)	7 / 8758 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal disorder			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 osteoarthritis			
subjects affected / exposed	3 / 6950 (0.04%)	5 / 6950 (0.07%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondyloarthropathy			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Still's disease adult onset			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Tendonitis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger finger			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Abscess			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 neck			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcaligenes infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal cellulitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	5 / 6950 (0.07%)	5 / 6950 (0.07%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerotic gangrene			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Atypical pneumonia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Bacteraemia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 2
Bacteriuria			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	8 / 6950 (0.12%)	7 / 6950 (0.10%)	10 / 8758 (0.11%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Bronchitis bacterial			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 6950 (0.01%)	4 / 6950 (0.06%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Candida infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida sepsis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Candiduria			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cavernous sinus thrombosis			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	8 / 6950 (0.12%)	14 / 6950 (0.20%)	11 / 8758 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Cholecystitis infective			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium bacteraemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 6950 (0.01%)	5 / 6950 (0.07%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Clostridium difficile infection			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colonic abscess			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cystitis			
subjects affected / exposed	4 / 6950 (0.06%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis klebsiella			



subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Device related infection			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	5 / 6950 (0.07%)	11 / 6950 (0.16%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Endocarditis			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Enterocolitis viral			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	3 / 6950 (0.04%)	7 / 6950 (0.10%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	1 / 3	0 / 7	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Escherichia infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungaemia			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Gastroenteritis			

subjects affected / exposed	8 / 6950 (0.12%)	8 / 6950 (0.12%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Gastroenteritis clostridial			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Gastroenteritis norovirus			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter gastritis			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster disseminated			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster oticus			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 dermal cyst			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Infection			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Infectious colitis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Intestinal gangrene			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Labyrinthitis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	2 / 6950 (0.03%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	4 / 6950 (0.06%)	8 / 6950 (0.12%)	4 / 8758 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Localised infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Medical device site infection			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Necrotising fasciitis streptococcal			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Neuroborreliosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 1
Oesophageal candidiasis			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Otitis media chronic			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 abscess			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 abscess			



subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	4 / 6950 (0.06%)	4 / 6950 (0.06%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 5
Peritonitis bacterial			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	70 / 6950 (1.01%)	81 / 6950 (1.17%)	96 / 8758 (1.10%)
occurrences causally related to treatment / all	0 / 70	0 / 81	0 / 96
deaths causally related to treatment / all	0 / 24	0 / 38	0 / 34
Pneumonia bacterial			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonia influenzal			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Pneumonia klebsiella			

subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pneumonia streptococcal			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 infection			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Postoperative abscess			
subjects affected / exposed	3 / 6950 (0.04%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Pseudomembranous colitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Pseudomonas infection			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psittacosis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Psoas abscess			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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 tuberculosis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Purulence			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	3 / 6950 (0.04%)	4 / 6950 (0.06%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyelonephritis acute			
subjects affected / exposed	4 / 6950 (0.06%)	0 / 6950 (0.00%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			

subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
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 moniliasis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 6950 (0.01%)	3 / 6950 (0.04%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis			
subjects affected / exposed	26 / 6950 (0.37%)	17 / 6950 (0.24%)	32 / 8758 (0.37%)
occurrences causally related to treatment / all	0 / 26	0 / 17	0 / 32
deaths causally related to treatment / all	0 / 16	0 / 11	0 / 21
Septic shock			
subjects affected / exposed	11 / 6950 (0.16%)	14 / 6950 (0.20%)	11 / 8758 (0.13%)
occurrences causally related to treatment / all	0 / 11	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 10	0 / 12	0 / 10
Sinusitis			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	4 / 6950 (0.06%)	1 / 6950 (0.01%)	5 / 8758 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Staphylococcal osteomyelitis			

subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular abscess			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethritis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	28 / 6950 (0.40%)	24 / 6950 (0.35%)	33 / 8758 (0.38%)
occurrences causally related to treatment / all	0 / 28	0 / 24	0 / 33
deaths causally related to treatment / all	0 / 2	0 / 6	0 / 4
Urinary tract infection bacterial			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	7 / 6950 (0.10%)	9 / 6950 (0.13%)	8 / 8758 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1
Vestibular neuronitis			
subjects affected / exposed	0 / 6950 (0.00%)	3 / 6950 (0.04%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Viral sepsis			

subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvitis			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	3 / 6950 (0.04%)	2 / 6950 (0.03%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	2 / 6950 (0.03%)	2 / 6950 (0.03%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Decreased appetite			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Dehydration			
subjects affected / exposed	8 / 6950 (0.12%)	8 / 6950 (0.12%)	12 / 8758 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Diabetes mellitus			
subjects affected / exposed	2 / 6950 (0.03%)	3 / 6950 (0.04%)	2 / 8758 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (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
Diabetic ketoacidosis			

subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Gout			
subjects affected / exposed	2 / 6950 (0.03%)	0 / 6950 (0.00%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercholesterolaemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 6950 (0.00%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hyperlipidaemia			
subjects affected / exposed	1 / 6950 (0.01%)	1 / 6950 (0.01%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			



subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
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	6 / 6950 (0.09%)	4 / 6950 (0.06%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	7 / 6950 (0.10%)	2 / 6950 (0.03%)	9 / 8758 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 6950 (0.03%)	5 / 6950 (0.07%)	3 / 8758 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	1 / 6950 (0.01%)	0 / 6950 (0.00%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Ketoacidosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed	1 / 6950 (0.01%)	2 / 6950 (0.03%)	1 / 8758 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Marasmus			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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
Metabolic acidosis			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	0 / 8758 (0.00%)
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	5 / 6950 (0.07%)	6 / 6950 (0.09%)	6 / 8758 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic acidosis			
subjects affected / exposed	0 / 6950 (0.00%)	1 / 6950 (0.01%)	0 / 8758 (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

<b>Serious adverse events</b>	Zoster-022/006 Pooled Placebo Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1521 / 8773 (17.34%)		
number of deaths (all causes)	580		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acral lentiginous melanoma			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute monocytic leukaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Acute myeloid leukaemia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Acute promyelocytic leukaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Adenocarcinoma gastric			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma pancreas			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Adrenal adenoma			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adrenal gland cancer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaplastic astrocytoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Anaplastic thyroid cancer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
B precursor type acute leukaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of bladder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of orbit			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign ovarian tumour			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign renal neoplasm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct adenocarcinoma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct cancer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
subjects affected / exposed	18 / 8773 (0.21%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 3		
Bladder cancer recurrent			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			

subjects affected / exposed	7 / 8773 (0.08%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 2			
Bladder papilloma				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma recurrent				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone cancer				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Brain cancer metastatic				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Brain neoplasm				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm benign				

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain neoplasm malignant			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Breast cancer			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Breast cancer metastatic			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchial carcinoma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour of the small bowel			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carcinoid tumour pulmonary			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Central nervous system neoplasm			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cervix carcinoma recurrent			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangiocarcinoma			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 5		
Cholesteatoma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon adenoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	12 / 8773 (0.14%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 7		
Colon cancer metastatic			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Colon neoplasm			



subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Diffuse large B-cell lymphoma				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Diffuse large B-cell lymphoma stage IV				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Endometrial adenocarcinoma				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Fallopian tube cancer				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Follicular thyroid cancer				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gallbladder cancer				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	6 / 8773 (0.07%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 4			
Gastrointestinal carcinoma				

subjects affected / exposed	0 / 8773 (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 / 8773 (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 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioblastoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Glioblastoma multiforme			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cancer			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 5		
Hepatic cancer metastatic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic neoplasm			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Hepatocellular carcinoma			

subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Hypergammaglobulinaemia benign monoclonal				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal adenocarcinoma				
subjects affected / exposed	0 / 8773 (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	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Invasive lobular breast carcinoma				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Invasive papillary breast carcinoma				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large cell lung cancer				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Large intestine benign neoplasm				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal cancer				

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal neoplasm			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Leukaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 5		
Lung adenocarcinoma metastatic			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Lung adenocarcinoma stage III			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung cancer metastatic			

subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 4			
Lung neoplasm				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 3			
Lung neoplasm malignant				
subjects affected / exposed	16 / 8773 (0.18%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 11			
Lymphoma				
subjects affected / exposed	5 / 8773 (0.06%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 3			
Malignant fibrous histiocytoma of bone				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant lymphoma unclassifiable high grade				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant mast cell neoplasm				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Malignant melanoma				
subjects affected / exposed	5 / 8773 (0.06%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Malignant melanoma in situ				

subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of ampulla of Vater				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of unknown primary site				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant palate neoplasm				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant pleural effusion				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningioma				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Mesothelioma				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to adrenals				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to bone				

subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Metastases to central nervous system				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Metastases to gastrointestinal tract				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Metastases to liver				
subjects affected / exposed	5 / 8773 (0.06%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 5			
Metastases to lung				
subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 2			
Metastases to lymph nodes				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Metastases to peritoneum				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to pleura				
subjects affected / exposed	0 / 8773 (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 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastasis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metastatic carcinoma of the bladder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic gastric cancer			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Metastatic malignant melanoma			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Metastatic neoplasm			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Metastatic renal cell carcinoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metastatic squamous cell carcinoma			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Myelodysplastic syndrome			



subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nasopharyngeal cancer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasm malignant			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 3		
Neoplasm prostate			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 8773 (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	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Non-small cell lung cancer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Non-small cell lung cancer stage IV			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Oesophageal adenocarcinoma			

subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Oesophageal adenocarcinoma metastatic				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal cancer metastatic				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Oesophageal carcinoma				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Oesophageal squamous cell carcinoma				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ovarian cancer				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer recurrent				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ovarian epithelial cancer				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian fibroma				

subjects affected / exposed	0 / 8773 (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	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	16 / 8773 (0.18%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 16		
Pancreatic carcinoma metastatic			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Pancreatic neoplasm			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic neuroendocrine tumour			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paraganglion neoplasm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid tumour benign			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour benign			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	23 / 8773 (0.26%)		
occurrences causally related to treatment / all	0 / 23		
deaths causally related to treatment / all	0 / 5		
Prostate cancer metastatic			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Prostate cancer recurrent			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer stage IV			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Prostatic adenoma			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Rectal adenoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal cancer			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Rectal cancer recurrent			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Renal cancer metastatic			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Renal cell carcinoma			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Renal cell carcinoma recurrent			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal neoplasm			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal oncocytoma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salivary gland cancer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sarcoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin cancer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer metastatic			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Small intestine adenocarcinoma			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sweat gland tumour			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Testicular neoplasm			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Throat cancer			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Thyroid cancer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transitional cell carcinoma metastatic			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Urethral neoplasm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine cancer			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Vulval cancer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			



Aneurysm				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aneurysm ruptured				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Angiodysplasia				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic aneurysm				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Aortic aneurysm rupture				
subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Aortic arteriosclerosis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic dilatation				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic dissection				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Aortic occlusion				

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic rupture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aortic stenosis			
subjects affected / exposed	10 / 8773 (0.11%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
Arterial disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 3		
Arteriovenous fistula			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bleeding varicose vein			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			

subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 5		
Deep vein thrombosis			
subjects affected / exposed	11 / 8773 (0.13%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 1		
Embolism			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral artery aneurysm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral artery occlusion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 1		
Haemodynamic instability			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Haemorrhage			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Hypertension			

subjects affected / exposed	32 / 8773 (0.36%)		
occurrences causally related to treatment / all	0 / 32		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Hypertensive emergency			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Inferior vena caval occlusion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intermittent claudication			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Internal haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labile hypertension			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microscopic polyangiitis			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Necrosis ischaemic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypertension			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Peripheral arterial occlusive disease			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Peripheral artery aneurysm			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral artery stenosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral artery thrombosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral embolism			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral vascular disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral venous disease			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock haemorrhagic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Temporal arteritis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thromboangiitis obliterans			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Varicose ulceration			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vasculitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis limb			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hospitalisation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal polypectomy			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Administration site erythema			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Administration site pain			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adverse drug reaction			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac death			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Chest discomfort			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chest pain			



subjects affected / exposed	22 / 8773 (0.25%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cyst			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	36 / 8773 (0.41%)		
occurrences causally related to treatment / all	0 / 36		
deaths causally related to treatment / all	0 / 36		
Device battery issue			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device deposit issue			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Device failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Device leakage			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device occlusion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drowning			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Fatigue			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Generalised oedema			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ill-defined disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incarcerated hernia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inflammation			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multi-organ failure			
subjects affected / exposed	12 / 8773 (0.14%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 11		
Non-cardiac chest pain			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Organ failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pyrexia			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Strangulated hernia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sudden cardiac death			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 6		
Sudden death			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 6		
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombosis in device			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Allergic granulomatous angiitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amyloidosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Breast dysplasia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatic obstruction			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Prostatomegaly			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectocele			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine polyp			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine prolapse			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal prolapse			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal ulceration			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 3		
Acute respiratory failure			

subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 4			
Aspiration				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Asthma				
subjects affected / exposed	6 / 8773 (0.07%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchiectasis				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis chronic				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	21 / 8773 (0.24%)			
occurrences causally related to treatment / all	0 / 21			
deaths causally related to treatment / all	0 / 9			
Diaphragmatic disorder				

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Emphysema			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Epistaxis			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemothorax			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperventilation			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Idiopathic pulmonary fibrosis			



subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Lung disorder			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Nasal polyps			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal septum deviation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural calcification			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	10 / 8773 (0.11%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Pleurisy			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleuritic pain			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 5		
Pneumothorax			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary cavitation			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary congestion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	28 / 8773 (0.32%)		
occurrences causally related to treatment / all	0 / 28		
deaths causally related to treatment / all	0 / 11		
Pulmonary fibrosis			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Pulmonary mass			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			

subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 3		
Respiratory arrest			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory distress			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Respiratory failure			
subjects affected / exposed	23 / 8773 (0.26%)		
occurrences causally related to treatment / all	0 / 23		
deaths causally related to treatment / all	0 / 15		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute psychosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Affective disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anxiety disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breathing-related sleep disorder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Completed suicide			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Confusional state			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Delirium febrile			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depressed mood			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			

subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Disorientation				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hallucination				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Major depression				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Mental disorder				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental disorder due to a general medical condition				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Panic attack				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Panic disorder				

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Schizoaffective disorder bipolar type			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Schizophrenia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Somatoform disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Anticoagulation drug level above therapeutic			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood glucose fluctuation			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
C-reactive protein increased			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemoglobin decreased			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heart rate decreased			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test abnormal			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Weight increased			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accidental overdose			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acetabulum fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aneurysm perforation			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ankle fracture			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Back injury			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone fissure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Burns third degree			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carbon monoxide poisoning			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cervical vertebral fracture			



subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Chemical poisoning			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest injury			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Comminuted fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Compression fracture			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Coronary artery reocclusion			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery restenosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis postoperative			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye penetration			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Face injury			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Femoral neck fracture			

subjects affected / exposed	10 / 8773 (0.11%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 1		
Femur fracture			
subjects affected / exposed	17 / 8773 (0.19%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 1		
Fibula fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foot fracture			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Forearm fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fractured sacrum			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gun shot wound			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hand fracture			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
Hip fracture			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Jaw fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Kidney contusion			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Ligament sprain			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			

subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Muscle rupture			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patella fracture			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Pneumothorax traumatic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Post procedural haemorrhage			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Post procedural pulmonary embolism			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound complication			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural intestinal perforation			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural pain			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pubis fracture			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Respiratory fume inhalation disorder			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Rib fracture			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Skin wound			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Snake bite			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Spinal cord injury			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal cord injury cervical			



subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal fracture			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Splenic rupture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sternal fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 2		
Subdural haemorrhage			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Synovial rupture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Thermal burn			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Traumatic fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic intracranial haemorrhage			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Ulna fracture			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Vascular graft occlusion			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound evisceration			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Wound haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Congenital cystic kidney disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertrophic cardiomyopathy			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyloric stenosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal dysplasia			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Acute left ventricular failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Acute myocardial infarction			
subjects affected / exposed	40 / 8773 (0.46%)		
occurrences causally related to treatment / all	0 / 40		
deaths causally related to treatment / all	0 / 21		
Angina pectoris			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	10 / 8773 (0.11%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Aortic valve disease			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic valve incompetence			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Arrhythmia			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 2		
Arrhythmia supraventricular			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerosis coronary artery			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Atrial fibrillation			
subjects affected / exposed	58 / 8773 (0.66%)		
occurrences causally related to treatment / all	0 / 58		
deaths causally related to treatment / all	0 / 0		
Atrial flutter			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
Atrial tachycardia			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Atrioventricular block complete			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Atrioventricular block first degree			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block second degree			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bradyarrhythmia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	20 / 8773 (0.23%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 20		
Cardiac disorder			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac failure			
subjects affected / exposed	72 / 8773 (0.82%)		
occurrences causally related to treatment / all	0 / 72		
deaths causally related to treatment / all	0 / 48		
Cardiac failure acute			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure chronic			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 4		
Cardiac failure congestive			
subjects affected / exposed	40 / 8773 (0.46%)		
occurrences causally related to treatment / all	0 / 40		
deaths causally related to treatment / all	0 / 14		
Cardiac tamponade			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac valve disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 4		
Cardiogenic shock			

subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiomegaly			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy alcoholic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiopulmonary failure			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiovascular deconditioning			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiovascular insufficiency			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronotropic incompetence			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			



subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cor pulmonale			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	31 / 8773 (0.35%)		
occurrences causally related to treatment / all	0 / 31		
deaths causally related to treatment / all	0 / 3		
Coronary artery insufficiency			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diastolic dysfunction			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extrasystoles			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart valve incompetence			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypertensive heart disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ischaemic cardiomyopathy			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Left ventricular failure			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Mitral valve stenosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	55 / 8773 (0.63%)		
occurrences causally related to treatment / all	0 / 55		
deaths causally related to treatment / all	0 / 31		
Myocardial ischaemia			

subjects affected / exposed	22 / 8773 (0.25%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 9		
Palpitations			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Right ventricular failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus arrest			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Sinus tachycardia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stress cardiomyopathy			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachyarrhythmia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular arrhythmia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Ventricular tachycardia			

subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aphasia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Balance disorder			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basilar artery thrombosis			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain injury			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Brain stem infarction			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain stem syndrome			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery occlusion			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Carotid sinus syndrome			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Central nervous system lesion			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar haemorrhage			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Cerebellar ischaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral artery embolism			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral artery thrombosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral atrophy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	11 / 8773 (0.13%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 10		
Cerebral infarction			
subjects affected / exposed	20 / 8773 (0.23%)		
occurrences causally related to treatment / all	1 / 20		
deaths causally related to treatment / all	0 / 7		
Cerebral ischaemia			

subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 3		
Cerebrospinal fluid leakage			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	38 / 8773 (0.43%)		
occurrences causally related to treatment / all	1 / 38		
deaths causally related to treatment / all	0 / 19		
Cerebrovascular disorder			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical myelopathy			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervicobrachial syndrome			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cognitive disorder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coma			



subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Dementia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Dementia Alzheimer's type			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Dementia with Lewy bodies			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic coma			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Drop attacks			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dural arteriovenous fistula			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspraxia			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 1		
Haemorrhage intracranial			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Haemorrhagic stroke			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
Haemorrhagic transformation stroke			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemiplegia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypertonia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Intracranial aneurysm			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intraventricular haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			

subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 1		
Lacunar infarction			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Memory impairment			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic encephalopathy			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Miller Fisher syndrome			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mixed dementia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Myasthenia gravis			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Myoclonus			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nerve compression			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neuralgia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neuritis cranial			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuropathy peripheral			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paralysis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parkinsonism			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Parkinson's disease			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Partial seizures			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post herpetic neuralgia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Progressive supranuclear palsy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Radiculopathy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Restless legs syndrome			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ruptured cerebral aneurysm			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Sciatica			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Senile dementia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Somnolence			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal claudication			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondylitic myelopathy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Subarachnoid haemorrhage			

subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 2		
Syncope			
subjects affected / exposed	24 / 8773 (0.27%)		
occurrences causally related to treatment / all	1 / 24		
deaths causally related to treatment / all	0 / 1		
Thalamic infarction			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thalamus haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombotic cerebral infarction			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Transient global amnesia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	19 / 8773 (0.22%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 0		
Trigeminal neuralgia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VIIIth nerve lesion			



subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VIIth nerve paralysis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular dementia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular encephalopathy			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	15 / 8773 (0.17%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 2		
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Disseminated intravascular coagulation			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic anaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Heparin-induced thrombocytopenia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypersplenism			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy mediastinal			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Microcytic anaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephrogenic anaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pernicious anaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic infarction			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Ear and labyrinth disorders			
Sudden hearing loss			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vestibular disorder			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amaurosis fugax			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cataract			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Choroidal effusion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diplopia			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glaucoma			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iridocele			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iritis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lens dislocation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ocular hypertension			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ocular vascular disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal degeneration			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Retinal haemorrhage			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vitreous haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Abdominal discomfort			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal strangulated hernia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal prolapse			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune pancreatitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Barrett's oesophagus			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic gastritis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colitis ulcerative			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia, obstructive			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal			



subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Duodenal ulcer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer perforation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterovesical fistula			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Faecal incontinence			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric haemorrhage			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastric perforation			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric polyps			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer haemorrhage			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer perforation			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Gastritis alcoholic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis haemorrhagic			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haematochezia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hiatus hernia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Incarcerated inguinal hernia			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incarcerated umbilical hernia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	13 / 8773 (0.15%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia strangulated			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal congestion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal infarction			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Intestinal ischaemia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Intestinal obstruction			

subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 3		
Intestinal perforation			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Large intestinal obstruction			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Large intestine polyp			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mesenteric artery embolism			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Mesenteric artery thrombosis			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesenteritis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mouth ulceration			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal spasm			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal ulcer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal ulcer haemorrhage			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic disorder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritoneal haemorrhage			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumoperitoneum			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Proctitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Rectal perforation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal polyp			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal prolapse			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal haemorrhage			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Salivary gland calculus			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestinal obstruction			



subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Volvulus			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Vomiting			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Bile duct obstruction			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary dilatation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary dyskinesia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Cholangitis acute			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	18 / 8773 (0.21%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			

subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	17 / 8773 (0.19%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 0		
Cholestasis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic hepatic failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cirrhosis alcoholic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug-induced liver injury			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gallbladder perforation			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hepatic cirrhosis			

subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Hepatic failure			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 2		
Hepatic function abnormal			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis alcoholic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic hepatitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Jaundice cholestatic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Actinic keratosis			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angioedema			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Dermal cyst			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatitis allergic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis contact			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatomyositis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic foot			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Drug eruption			

subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eczema				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Leukoplakia				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lichen planus				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psoriasis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin necrosis				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stasis dermatitis				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urticaria				

subjects affected / exposed	0 / 8773 (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	22 / 8773 (0.25%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 7		
Acute prerenal failure			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder neck obstruction			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder perforation			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bladder prolapse			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Calculus ureteric			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	13 / 8773 (0.15%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 4		
Cystitis haemorrhagic			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis interstitial			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic nephropathy			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysuria			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephroangiosclerosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			



subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Nephropathy toxic			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neurogenic bladder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prerenal failure			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal artery occlusion			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cyst			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	14 / 8773 (0.16%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 5		
Renal hypertension			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal mass			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress urinary incontinence			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tubulointerstitial nephritis			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Urethral haemorrhage			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral meatus stenosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Urinary tract disorder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Basedow's disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cushingoid			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism primary			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypopituitarism			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Acquired claw toe			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthrofibrosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthropathy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back pain			

subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	0 / 8773 (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 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chondrocalcinosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chondropathy			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foot deformity			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gouty arthritis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc disorder			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			

subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Joint effusion			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniscal degeneration			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mixed connective tissue disease			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscle spasms			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myalgia			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myositis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	20 / 8773 (0.23%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 0		
Osteochondritis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoporosis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Osteoporotic fracture			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			

subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				
subjects affected / exposed	5 / 8773 (0.06%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Polymyositis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pseudarthrosis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Rheumatoid arthritis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sjogren's syndrome				



subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal column stenosis			
subjects affected / exposed	7 / 8773 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Spinal disorder			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal osteoarthritis			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Spinal pain			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spondyloarthropathy			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spondylolisthesis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Still's disease adult onset			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovial cyst			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Systemic lupus erythematosus			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Tendonitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tenosynovitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trigger finger			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acarodermatitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcaligenes infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fistula infection			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anorectal cellulitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendiceal abscess			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			

subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriosclerotic gangrene			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis infective			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial sepsis			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
<b>Bacteriuria</b>			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Biliary tract infection</b>			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Bronchitis</b>			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 1		
<b>Bronchitis bacterial</b>			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Bronchopneumonia</b>			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 2		
<b>Candida infection</b>			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Candida sepsis</b>			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
<b>Candiduria</b>			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cavernous sinus thrombosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	16 / 8773 (0.18%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 1		
Cholecystitis infective			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium bacteraemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 1		
Clostridium difficile infection			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Colonic abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis klebsiella			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic foot infection			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	13 / 8773 (0.15%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 2		
Empyema			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Encephalitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalitis viral			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Endocarditis			

subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis viral				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epididymitis				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	9 / 8773 (0.10%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 1			
Escherichia infection				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fungaemia				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gangrene				



subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	8 / 8773 (0.09%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis clostridial			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Gastroenteritis norovirus			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Gastroenteritis salmonella			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Graft infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma infection			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Helicobacter gastritis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Helicobacter infection			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis A			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes simplex			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Herpes zoster disseminated			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster meningitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster oticus			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incision site infection			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected dermal cyst			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infected skin ulcer			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Infectious colitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Intestinal gangrene			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Klebsiella bacteraemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Klebsiella sepsis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Labyrinthitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Liver abscess			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lobar pneumonia			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 3		
Localised infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			

subjects affected / exposed	5 / 8773 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lung abscess				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	2 / 8773 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Medical device site infection				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Necrotising fasciitis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Necrotising fasciitis streptococcal				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Neuroborreliosis				

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenic sepsis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal candidiasis			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Orchitis			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media chronic			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ovarian abscess			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periodontitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	5 / 8773 (0.06%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 2		
Peritonitis bacterial			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	93 / 8773 (1.06%)		
occurrences causally related to treatment / all	0 / 93		
deaths causally related to treatment / all	0 / 42		
Pneumonia bacterial			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia influenzal			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia klebsiella			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Pneumonia pneumococcal			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia streptococcal			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 1		
Postoperative abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pseudomembranous colitis			



subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Pseudomonas infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psittacosis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psoas abscess			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Purulence			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	6 / 8773 (0.07%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rectal abscess			

subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory moniliasis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Sepsis			
subjects affected / exposed	26 / 8773 (0.30%)		
occurrences causally related to treatment / all	0 / 26		
deaths causally related to treatment / all	0 / 16		
Septic shock			
subjects affected / exposed	16 / 8773 (0.18%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 13		
Sinusitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Soft tissue infection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal osteomyelitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Streptococcal sepsis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Superinfection			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Testicular abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			

subjects affected / exposed	0 / 8773 (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	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection bacterial				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethritis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	30 / 8773 (0.34%)			
occurrences causally related to treatment / all	0 / 30			
deaths causally related to treatment / all	0 / 6			
Urinary tract infection bacterial				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	9 / 8773 (0.10%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 3			
Vestibular neuronitis				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Viral infection				

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Viral sepsis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulvitis			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Decreased appetite			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	10 / 8773 (0.11%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	4 / 8773 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			

subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Gout			
subjects affected / exposed	0 / 8773 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercholesterolaemia			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	2 / 8773 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Hyperlipidaemia			

subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	4 / 8773 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	3 / 8773 (0.03%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	7 / 8773 (0.08%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Hypophagia				
subjects affected / exposed	0 / 8773 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ketoacidosis				
subjects affected / exposed	1 / 8773 (0.01%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lactic acidosis				

subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	3 / 8773 (0.03%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Marasmus			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Metabolic acidosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Type 2 diabetes mellitus			
subjects affected / exposed	9 / 8773 (0.10%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Uraemic acidosis			
subjects affected / exposed	1 / 8773 (0.01%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

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

<b>Non-serious adverse events</b>	Zoster-022 GSK1437173A Group	Zoster-022 Placebo Group	Zoster-022/006 Pooled GSK1437173A Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4080 / 6950 (58.71%)	853 / 6950 (12.27%)	5543 / 8758 (63.29%)
Nervous system disorders			
Headache			



subjects affected / exposed	586 / 6950 (8.43%)	243 / 6950 (3.50%)	1118 / 8758 (12.77%)
occurrences (all)	717	307	1413
General disorders and administration site conditions			
Chills			
subjects affected / exposed	353 / 6950 (5.08%)	39 / 6950 (0.56%)	718 / 8758 (8.20%)
occurrences (all)	415	46	862
Fatigue			
subjects affected / exposed	474 / 6950 (6.82%)	169 / 6950 (2.43%)	1135 / 8758 (12.96%)
occurrences (all)	592	192	1494
Injection site erythema			
subjects affected / exposed	864 / 6950 (12.43%)	27 / 6950 (0.39%)	872 / 8758 (9.96%)
occurrences (all)	1150	29	1162
Injection site pain			
subjects affected / exposed	1975 / 6950 (28.42%)	148 / 6950 (2.13%)	1990 / 8758 (22.72%)
occurrences (all)	2762	165	2783
Injection site swelling			
subjects affected / exposed	613 / 6950 (8.82%)	16 / 6950 (0.23%)	616 / 8758 (7.03%)
occurrences (all)	773	18	776
Pain			
subjects affected / exposed	428 / 6950 (6.16%)	60 / 6950 (0.86%)	1644 / 8758 (18.77%)
occurrences (all)	669	67	2670
Pyrexia			
subjects affected / exposed	535 / 6950 (7.70%)	52 / 6950 (0.75%)	800 / 8758 (9.13%)
occurrences (all)	633	56	926
Swelling			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	521 / 8758 (5.95%)
occurrences (all)	0	0	701
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 6950 (0.00%)	0 / 6950 (0.00%)	871 / 8758 (9.95%)
occurrences (all)	0	0	1208
Musculoskeletal and connective tissue disorders			
Myalgia			

subjects affected / exposed	378 / 6950 (5.44%)	99 / 6950 (1.42%)	1017 / 8758 (11.61%)
occurrences (all)	472	113	1413

<b>Non-serious adverse events</b>	Zoster-022/006 Pooled Placebo Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3027 / 8773 (34.50%)		
Nervous system disorders			
Headache			
subjects affected / exposed	464 / 8773 (5.29%)		
occurrences (all)	573		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	128 / 8773 (1.46%)		
occurrences (all)	147		
Fatigue			
subjects affected / exposed	420 / 8773 (4.79%)		
occurrences (all)	501		
Injection site erythema			
subjects affected / exposed	27 / 8773 (0.31%)		
occurrences (all)	29		
Injection site pain			
subjects affected / exposed	153 / 8773 (1.74%)		
occurrences (all)	170		
Injection site swelling			
subjects affected / exposed	16 / 8773 (0.18%)		
occurrences (all)	18		
Pain			
subjects affected / exposed	217 / 8773 (2.47%)		
occurrences (all)	254		
Pyrexia			
subjects affected / exposed	102 / 8773 (1.16%)		
occurrences (all)	107		
Swelling			
subjects affected / exposed	25 / 8773 (0.28%)		
occurrences (all)	27		

Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all)	44 / 8773 (0.50%) 49		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	286 / 8773 (3.26%) 343		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported