



## Clinical trial results:

**A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to valsartan, on morbidity and mortality in heart failure patients (NYHA Class II-IV) with preserved ejection fraction**

### Summary

EudraCT number	2013-001747-31
Trial protocol	SK HU AT BG DE ES NO GB NL CZ IT SE BE DK GR FI HR PL SI
Global end of trial date	07 June 2019

### Results information

Result version number	v1 (current)
This version publication date	21 June 2020
First version publication date	21 June 2020

### Trial information

#### Trial identification

Sponsor protocol code	CLCZ696D2301
-----------------------	--------------

#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01920711
WHO universal trial number (UTN)	-

Notes:

### Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Clinical Disclosure Office, 41 613241111, Novartis.email@novartis.com

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 June 2019
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 June 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to compare sacubitril/valsartan to valsartan in reducing the rate of the composite endpoint of cardiovascular (CV) death and total (first and recurrent) heart failure (HF) hospitalizations, in HF patients (NYHA Class II-IV) with preserved ejection fraction (LVEF  $\geq$  45%).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 July 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 110
Country: Number of subjects enrolled	Australia: 24
Country: Number of subjects enrolled	Austria: 42
Country: Number of subjects enrolled	Belgium: 65
Country: Number of subjects enrolled	Brazil: 109
Country: Number of subjects enrolled	Bulgaria: 363
Country: Number of subjects enrolled	Canada: 79
Country: Number of subjects enrolled	China: 265
Country: Number of subjects enrolled	Colombia: 12
Country: Number of subjects enrolled	Croatia: 60
Country: Number of subjects enrolled	Czech Republic: 241
Country: Number of subjects enrolled	Denmark: 36
Country: Number of subjects enrolled	Finland: 8
Country: Number of subjects enrolled	France: 38
Country: Number of subjects enrolled	Germany: 388
Country: Number of subjects enrolled	Greece: 63
Country: Number of subjects enrolled	Guatemala: 47
Country: Number of subjects enrolled	Hungary: 252

Country: Number of subjects enrolled	India: 79
Country: Number of subjects enrolled	Israel: 83
Country: Number of subjects enrolled	Italy: 204
Country: Number of subjects enrolled	Japan: 79
Country: Number of subjects enrolled	Korea, Republic of: 48
Country: Number of subjects enrolled	Mexico: 60
Country: Number of subjects enrolled	Netherlands: 102
Country: Number of subjects enrolled	Norway: 14
Country: Number of subjects enrolled	Peru: 32
Country: Number of subjects enrolled	Philippines: 33
Country: Number of subjects enrolled	Poland: 180
Country: Number of subjects enrolled	Romania: 110
Country: Number of subjects enrolled	Russian Federation: 170
Country: Number of subjects enrolled	Serbia: 19
Country: Number of subjects enrolled	Singapore: 20
Country: Number of subjects enrolled	Slovakia: 310
Country: Number of subjects enrolled	Slovenia: 13
Country: Number of subjects enrolled	South Africa: 70
Country: Number of subjects enrolled	Spain: 254
Country: Number of subjects enrolled	Sweden: 41
Country: Number of subjects enrolled	Switzerland: 12
Country: Number of subjects enrolled	Taiwan: 61
Country: Number of subjects enrolled	Turkey: 23
Country: Number of subjects enrolled	United Kingdom: 123
Country: Number of subjects enrolled	United States: 480
Worldwide total number of subjects	4822
EEA total number of subjects	2907

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	830
From 65 to 84 years	3992
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

10, 359 patients were screened. 5747 patients were in the Enrolled set. 5746 patients entered valsartan run-in epoch, 5205 patients entered LCZ696 run-in epoch. 4822 patients who completed run-in were randomized at 755 sites in 43 countries. 2419 into the LCZ696 treatment group and 2403 into the valsartan treatment group.

### Pre-assignment

Screening details:

10, 359 patients were screened. 5747 patients were in the Enrolled set. 5746 patients entered valsartan run-in epoch, 5205 patients entered LCZ696 run-in epoch. 4822 patients who completed run-in were randomized at 755 sites in 43 countries. 2419 into the LCZ696 treatment group and 2403 into the valsartan treatment group.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	LCZ696

Arm description:

Single Blind Run-in Period (3-8 weeks): Prior optional valsartan run-in 40 mg bid for 1-2 weeks for some patients. followed by Valsartan 80 mg bid for 1-2 weeks followed by LCZ696 100 mg bid for 2-4 weeks prior to randomization into the Double Blind period (up to 57 months). Patients could only be randomized from the run-in period if they met all of the run-in safety criteria. Target dose of LCZ696 during the double blind period was 200 mg bid

Arm type	Experimental
Investigational medicinal product name	Sacubitiril/Valsartan
Investigational medicinal product code	LCZ696
Other name	Entresto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg

Investigational medicinal product name	Sacubitiril/Valsartan
Investigational medicinal product code	LCZ696
Other name	Entresto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg

Investigational medicinal product name	Sacubitiril/Valsartan
Investigational medicinal product code	LCZ696
Other name	Entresto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

200 mg

Investigational medicinal product name	Sacubitril/Valsartan
Investigational medicinal product code	LCZ696
Other name	Entresto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo to match 50 mg, 100mg, 200 mg

<b>Arm title</b>	Valsartan
------------------	-----------

Arm description:

Single Blind Run-in Period (3-8 weeks): Prior optional valsartan run-in 40 mg bid for 1-2 weeks for some patients, followed by Valsartan 80 mg bid. for 1-2 weeks followed by LCZ696 100 mg bid for 2-4 weeks prior to randomization into the Double Blind period (up to 57 months). Patients could only be randomized from the run-in period if they met all of the run-in safety criteria. Target dose of Valsartan during the double blind period was 160 mg bid

Arm type	Experimental
Investigational medicinal product name	Valsartan
Investigational medicinal product code	
Other name	Diovan
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

40 mg

Investigational medicinal product name	Valsartan
Investigational medicinal product code	
Other name	Diovan
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg

Investigational medicinal product name	Valsartan
Investigational medicinal product code	
Other name	Diovan
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

160 mg

Investigational medicinal product name	Valsartan
Investigational medicinal product code	
Other name	Diovan
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo to match 40 mg, 80 mg, 160 mg

<b>Number of subjects in period 1</b>	LCZ696	Valsartan
Started	2419	2403
Completed	2055	2030
Not completed	364	373
Adverse event, serious fatal	347	356
Consent withdrawn by subject	4	3
Lost to follow-up	13	14

## Baseline characteristics

### Reporting groups

Reporting group title	LCZ696
-----------------------	--------

Reporting group description:

Single Blind Run-in Period (3-8 weeks): Prior optional valsartan run-in 40 mg bid for 1-2 weeks for some patients, followed by Valsartan 80 mg bid for 1-2 weeks followed by LCZ696 100 mg bid for 2-4 weeks prior to randomization into the Double Blind period (up to 57 months). Patients could only be randomized from the run-in period if they met all of the run-in safety criteria. Target dose of LCZ696 during the double blind period was 200 mg bid

Reporting group title	Valsartan
-----------------------	-----------

Reporting group description:

Single Blind Run-in Period (3-8 weeks): Prior optional valsartan run-in 40 mg bid for 1-2 weeks for some patients, followed by Valsartan 80 mg bid, for 1-2 weeks followed by LCZ696 100 mg bid for 2-4 weeks prior to randomization into the Double Blind period (up to 57 months). Patients could only be randomized from the run-in period if they met all of the run-in safety criteria. Target dose of Valsartan during the double blind period was 160 mg bid

Reporting group values	LCZ696	Valsartan	Total
Number of subjects	2419	2403	4822
Age Categorical Units:			
<=18 years	0	0	0
Between 18 and 65 years	415	415	830
>=65 years	2004	1988	3992
Sex: Female, Male Units: Participants			
Female	1247	1244	2491
Male	1172	1159	2331
Race/Ethnicity, Customized Units: Subjects			
Caucasian	1975	1958	3933
Black	52	50	102
Asian	297	310	607
Native American	28	23	51
Pacific Islander	0	1	1
Other	67	61	128

## End points

### End points reporting groups

Reporting group title	LCZ696
-----------------------	--------

Reporting group description:

Single Blind Run-in Period (3-8 weeks): Prior optional valsartan run-in 40 mg bid for 1-2 weeks for some patients. followed by Valsartan 80 mg bid for 1-2 weeks followed by LCZ696 100 mg bid for 2-4 weeks prior to randomization into the Double Blind period (up to 57 months). Patients could only be randomized from the run-in period if they met all of the run-in safety criteria. Target dose of LCZ696 during the double blind period was 200 mg bid

Reporting group title	Valsartan
-----------------------	-----------

Reporting group description:

Single Blind Run-in Period (3-8 weeks): Prior optional valsartan run-in 40 mg bid for 1-2 weeks for some patients, followed by Valsartan 80 mg bid. for 1-2 weeks followed by LCZ696 100 mg bid for 2-4 weeks prior to randomization into the Double Blind period (up to 57 months). Patients could only be randomized from the run-in period if they met all of the run-in safety criteria. Target dose of Valsartan during the double blind period was 160 mg bid

### Primary: Cumulative number of primary composite events of cardiovascular (CV) death and total (first and recurrent) HF hospitalizations.

End point title	Cumulative number of primary composite events of cardiovascular (CV) death and total (first and recurrent) HF hospitalizations.
-----------------	---

End point description:

The primary objective of this study is to compare LCZ696 to valsartan in reducing the rate of the composite endpoint of CV death and total (first and recurrent) HF hospitalizations, in HF patients (New York Heart Association [NYHA] Class II-IV) with preserved ejection fraction (left ventricular ejection fraction [LVEF]  $\geq 45\%$ ). The treatment arm with the lower rate of events will be deemed as having a successful response.

End point type	Primary
----------------	---------

End point timeframe:

Total follow up time (up to 57 months)

End point values	LCZ696	Valsartan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2407	2389		
Units: Number of Events				
Primary Composite Events	894	1009		
Total Hospitalizations for heart failure	690	797		
Cardiovascular death	204	212		

### Statistical analyses

Statistical analysis title	Primary Composite Events
----------------------------	--------------------------

Statistical analysis description:

Primary Composite Events

Comparison groups	LCZ696 v Valsartan
-------------------	--------------------

Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0587 <sup>[1]</sup>
Method	Proportional Rates Model (LWYY)
Parameter estimate	Rate Ratio
Point estimate	0.8698
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7526
upper limit	1.0052

Notes:

[1] - 1-sided p-value 0.0294

<b>Statistical analysis title</b>	Total Hospitalizations for heart failure
Statistical analysis description: Total Hospitalizations for heart failure	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0556 <sup>[2]</sup>
Method	Joint Frality Model
Parameter estimate	Rate Ratio
Point estimate	0.8511
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7216
upper limit	1.0039

Notes:

[2] - 1-sided p-value 0.0278

<b>Statistical analysis title</b>	Cardiovascular Death
Statistical analysis description: Cardiovascular Death	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6241 <sup>[3]</sup>
Method	Cox's proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9531
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7863
upper limit	1.1551

Notes:

[3] - 1-sided p-value 0.3120

### Secondary: Change in the clinical summary score from baseline to Month 8 by Kansas City Cardiomyopathy Questionnaire (KCCQ)

End point title	Change in the clinical summary score from baseline to Month 8 by Kansas City Cardiomyopathy Questionnaire (KCCQ)
-----------------	--

End point description:

The KCCQ is a validated instrument for self-assessment of quality of life and health status in heart failure (HF) patients. The clinical summary score, which is derived from the physical limitations and heart failure (HF) symptoms domains of the KCCQ is a valid measure for assessing the patient's health aspects that may be influenced by CV medications. Evaluation of change from baseline to month 8 in KCCQ a most sensitive, specific, and responsive health-related quality of life measure for heart failure symptoms and physical limitations.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline, 8 months

End point values	LCZ696	Valsartan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2407	2389		
Units: Points on a scale				
least squares mean (standard error)	-1.5073 ( $\pm$ 0.3709)	-2.5338 ( $\pm$ 0.3729)		

### Statistical analyses

Statistical analysis title	Clinical Summary Score
----------------------------	------------------------

Statistical analysis description:

Clinical Summary Score

Comparison groups	LCZ696 v Valsartan
-------------------	--------------------

Number of subjects included in analysis	4796
---	------

Analysis specification	Pre-specified
------------------------	---------------

Analysis type	
---------------	--

P-value	= 0.051
---------	---------

Method	Mixed models analysis
--------	-----------------------

Parameter estimate	Least Squares Mean of Difference
--------------------	----------------------------------

Point estimate	1.0264
----------------	--------

Confidence interval

level	95 %
-------	------

sides	2-sided
-------	---------

lower limit	-0.0047
-------------	---------

upper limit	2.0576
-------------	--------

### Secondary: Change from baseline to Month 8 in New York Heart Association (NYHA)

**functional class**

End point title	Change from baseline to Month 8 in New York Heart Association (NYHA) functional class
-----------------	---

End point description:

Evaluation of change from baseline to Month 8 in NYHA functional class, a well established grading scale used to classify a heart failure's (HF) patients' level of functionality based on the signs and symptoms of HF exhibited by the patient.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline, 8 months

End point values	LCZ696	Valsartan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2407	2389		
Units: Number of Participants				
Improved (n=2316, 2302)	347	289		
Unchanged (n=2316, 2302)	1767	1792		
Worsened (n=2316, 2302)	202	221		

**Statistical analyses**

<b>Statistical analysis title</b>	NYHA Class Change
-----------------------------------	-------------------

Statistical analysis description:

NYHA Class Change

Comparison groups	LCZ696 v Valsartan
-------------------	--------------------

Number of subjects included in analysis	4796
---	------

Analysis specification	Pre-specified
------------------------	---------------

Analysis type

P-value	= 0.0035
---------	----------

Method	Repeated measures cumulative odds model
--------	---

Parameter estimate	Odds ratio (OR)
--------------------	-----------------

Point estimate	1.4475
----------------	--------

Confidence interval

level	95 %
-------	------

sides	2-sided
-------	---------

lower limit	1.1294
-------------	--------

upper limit	1.8552
-------------	--------

**Secondary: Time to first occurrence of a composite renal endpoint**

End point title	Time to first occurrence of a composite renal endpoint
-----------------	--

End point description:

Analysis of composite renal endpoint defined as renal death, or reaching ESRD, or  $\geq 50\%$  decline in eGFR relative to baseline, using Cox's proportional hazards model.

End point type	Secondary
----------------	-----------

End point timeframe:

Randomization to total follow-up time (up to 57 months)

<b>End point values</b>	LCZ696	Valsartan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2407	2389		
Units: Participants with first event				
Composite renal endpoint	33	64		
Renal Death	1	1		
Reaching ESRD	7	12		
$\geq 50\%$ decline in eGFR from baseline	27	60		

### Statistical analyses

<b>Statistical analysis title</b>	Composite renal endpoint
Statistical analysis description: Composite renal endpoint	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0014
Method	Cox's proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.5041
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3312
upper limit	0.7673

<b>Statistical analysis title</b>	Renal Death
Statistical analysis description: Renal Death	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9588
Method	Cox's proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9295

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.0581
upper limit	14.861

<b>Statistical analysis title</b>	Reaching ESRD
Statistical analysis description: Reaching ESRD	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2484
Method	Cox's proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.5774
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2272
upper limit	1.4672

<b>Statistical analysis title</b>	>=50% decline in eGFR from baseline
Statistical analysis description: >=50% decline in eGFR from baseline	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0004
Method	Cox's proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.4407
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2798
upper limit	0.6942

### Secondary: Time to all-cause mortality

End point title	Time to all-cause mortality
-----------------	-----------------------------

End point description:

Analysis for all-cause mortality using Cox's proportional hazards model.

End point type	Secondary
End point timeframe:	
Randomization to total follow up time (up to 57 months)	

<b>End point values</b>	LCZ696	Valsartan		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2407	2389		
Units: Participants with 1st event	342	349		

## Statistical analyses

<b>Statistical analysis title</b>	All-cause mortality
Statistical analysis description:	
All-cause mortality	
Comparison groups	LCZ696 v Valsartan
Number of subjects included in analysis	4796
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6846
Method	Cox's proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9696
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8352
upper limit	1.1255

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose of study treatment until end of study treatment plus 30 days post treatment, up to maximum duration of approx. 5 years.

Adverse event reporting additional description:

Any sign or symptom that occurs during the study treatment plus the 30 days post treatment. Safety set included all randomized patients minus 1 patient who did not receive study drug: 4821 patients.

Assessment type	Systematic
-----------------	------------

### Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	22.0
--------------------	------

### Reporting groups

Reporting group title	Valsartan
-----------------------	-----------

Reporting group description:

Valsartan

Reporting group title	LCZ696
-----------------------	--------

Reporting group description:

LCZ696

Reporting group title	All patients
-----------------------	--------------

Reporting group description:

All patients

<b>Serious adverse events</b>	Valsartan	LCZ696	All patients
Total subjects affected by serious adverse events			
subjects affected / exposed	1416 / 2402 (58.95%)	1424 / 2419 (58.87%)	2840 / 4821 (58.91%)
number of deaths (all causes)	357	347	704
number of deaths resulting from adverse events	5	5	10
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Acute myeloid leukaemia			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute promyelocytic leukaemia			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Adenocarcinoma			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Adenocarcinoma gastric			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Adenocarcinoma of colon			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal cancer stage 0			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	11 / 2402 (0.46%)	11 / 2419 (0.45%)	22 / 4821 (0.46%)
occurrences causally related to treatment / all	0 / 12	1 / 14	1 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign gastrointestinal neoplasm			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Benign pancreatic neoplasm</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Bile duct cancer</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
<b>Bladder cancer</b>			
subjects affected / exposed	5 / 2402 (0.21%)	2 / 2419 (0.08%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Bladder neoplasm</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bladder transitional cell carcinoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bone cancer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Bowen's disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Brain neoplasm</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Brain neoplasm malignant</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Breast angiosarcoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Breast cancer</b>			
subjects affected / exposed	8 / 2402 (0.33%)	6 / 2419 (0.25%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 15
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Breast neoplasm</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchial carcinoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Carcinoma in situ of skin</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Central nervous system lymphoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Cholangiocarcinoma</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	4 / 2402 (0.17%)	5 / 2419 (0.21%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	1 / 4	0 / 5	1 / 9
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Colon cancer metastatic			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Colon neoplasm			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Colorectal cancer			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Endometrial adenocarcinoma			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Fibroma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Gallbladder neoplasm			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 5
Gastric neoplasm			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal carcinoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal neoplasm</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal stromal tumour</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Gastrointestinal tract adenoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Glioblastoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemangioma of liver</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatic cancer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
<b>Hepatic cancer metastatic</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Hepatic neoplasm</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Hepatocellular carcinoma</b>			
subjects affected / exposed	2 / 2402 (0.08%)	5 / 2419 (0.21%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
<b>Hormone-refractory prostate cancer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intestinal adenocarcinoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Invasive breast carcinoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Invasive lobular breast carcinoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Invasive papillary breast carcinoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Kaposi's sarcoma</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lung carcinoma cell type unspecified stage II			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lung neoplasm malignant			
subjects affected / exposed	10 / 2402 (0.42%)	8 / 2419 (0.33%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 10	0 / 8	0 / 18
deaths causally related to treatment / all	0 / 3	0 / 4	0 / 7
Lymphoma			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoproliferative disorder			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant mediastinal neoplasm			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Malignant melanoma			
subjects affected / exposed	6 / 2402 (0.25%)	7 / 2419 (0.29%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	1 / 6	0 / 7	1 / 13
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Malignant neoplasm of unknown primary site			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Malignant pleural effusion</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Mantle cell lymphoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mediastinum neoplasm</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Meningioma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mesothelioma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Metastases to bone</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Metastases to central nervous system</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Metastases to liver</b>			

subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Metastases to lung			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Metastases to lymph nodes			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Metastasis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metastatic carcinoma of the bladder			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic lymphoma			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Metastatic malignant melanoma			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Monoclonal gammopathy			

subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	1 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myelodysplastic syndrome</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Myeloid leukaemia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Myeloproliferative neoplasm</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neoplasm malignant</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Neoplasm skin</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Non-Hodgkin's lymphoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Non-small cell lung cancer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Oesophageal adenocarcinoma</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal carcinoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oncologic complication</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Oral haemangioma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oropharyngeal cancer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Oropharyngeal squamous cell carcinoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Ovarian cancer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Ovarian epithelial cancer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatic carcinoma</b>			

subjects affected / exposed	2 / 2402 (0.08%)	4 / 2419 (0.17%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 5
<b>Pancreatic neoplasm</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Papillary thyroid cancer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Papilloma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Parathyroid tumour benign</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Penile cancer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Plasma cell myeloma</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Prostate cancer</b>			
subjects affected / exposed	8 / 2402 (0.33%)	7 / 2419 (0.29%)	15 / 4821 (0.31%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Prostate cancer metastatic</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	4 / 2402 (0.17%)	6 / 2419 (0.25%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Rectal cancer metastatic			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Rectal cancer recurrent			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal neoplasm			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			

subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal neoplasm</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sarcoma uterus</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Schwannoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Seborrhoeic keratosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin cancer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin neoplasm bleeding</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Small cell lung cancer</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Squamous cell carcinoma</b>			

subjects affected / exposed	8 / 2402 (0.33%)	6 / 2419 (0.25%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	0 / 10	0 / 7	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 4	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Transitional cell carcinoma			
subjects affected / exposed	4 / 2402 (0.17%)	0 / 2419 (0.00%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour compression			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour embolism			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Ureteral neoplasm			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Uterine cancer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Uterine leiomyoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vaginal adenocarcinoma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vaginal cancer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Waldenstrom's macroglobulinaemia</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vascular disorders</b>			
<b>Accelerated hypertension</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Angiopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aortic aneurysm</b>			

subjects affected / exposed	8 / 2402 (0.33%)	2 / 2419 (0.08%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aortic aneurysm rupture</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
<b>Aortic dissection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aortic rupture</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aortic stenosis</b>			
subjects affected / exposed	12 / 2402 (0.50%)	13 / 2419 (0.54%)	25 / 4821 (0.52%)
occurrences causally related to treatment / all	0 / 12	0 / 13	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Aortic thrombosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arterial occlusive disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arteriosclerosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bleeding varicose vein</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Blood pressure fluctuation</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Circulatory collapse</b>			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	1 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Deep vein thrombosis</b>			
subjects affected / exposed	7 / 2402 (0.29%)	4 / 2419 (0.17%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	1 / 8	0 / 4	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dry gangrene</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Essential hypertension</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Extremity necrosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haematoma</b>			
subjects affected / exposed	8 / 2402 (0.33%)	7 / 2419 (0.29%)	15 / 4821 (0.31%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Haemorrhage</b>			

subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemorrhagic infarction</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypertension</b>			
subjects affected / exposed	25 / 2402 (1.04%)	16 / 2419 (0.66%)	41 / 4821 (0.85%)
occurrences causally related to treatment / all	0 / 30	0 / 16	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypertensive crisis</b>			
subjects affected / exposed	8 / 2402 (0.33%)	4 / 2419 (0.17%)	12 / 4821 (0.25%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypertensive emergency</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Hypertensive urgency</b>			
subjects affected / exposed	1 / 2402 (0.04%)	6 / 2419 (0.25%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypotension</b>			
subjects affected / exposed	47 / 2402 (1.96%)	52 / 2419 (2.15%)	99 / 4821 (2.05%)
occurrences causally related to treatment / all	22 / 52	24 / 60	46 / 112
deaths causally related to treatment / all	0 / 1	1 / 3	1 / 4
<b>Hypovolaemic shock</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Iliac artery embolism</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
Jugular vein thrombosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed	4 / 2402 (0.17%)	0 / 2419 (0.00%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Orthostatic hypertension			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	9 / 2402 (0.37%)	5 / 2419 (0.21%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	3 / 9	1 / 5	4 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			

subjects affected / exposed	7 / 2402 (0.29%)	18 / 2419 (0.74%)	25 / 4821 (0.52%)
occurrences causally related to treatment / all	0 / 9	0 / 19	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral coldness			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	1 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	7 / 2402 (0.29%)	8 / 2419 (0.33%)	15 / 4821 (0.31%)
occurrences causally related to treatment / all	0 / 8	0 / 9	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Peripheral vascular disorder			

subjects affected / exposed	2 / 2402 (0.08%)	5 / 2419 (0.21%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post thrombotic syndrome			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	5 / 2402 (0.21%)	2 / 2419 (0.08%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Subclavian artery stenosis			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery thrombosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	21 / 2402 (0.87%)	12 / 2419 (0.50%)	33 / 4821 (0.68%)
occurrences causally related to treatment / all	3 / 23	0 / 12	3 / 35
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiac death			
subjects affected / exposed	6 / 2402 (0.25%)	3 / 2419 (0.12%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	1 / 6	0 / 3	1 / 9
deaths causally related to treatment / all	1 / 6	0 / 3	1 / 9
Catheter site haemorrhage			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			

subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Chest pain</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Concomitant disease progression</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Condition aggravated</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Death</b>			
subjects affected / exposed	23 / 2402 (0.96%)	34 / 2419 (1.41%)	57 / 4821 (1.18%)
occurrences causally related to treatment / all	0 / 23	0 / 34	0 / 57
deaths causally related to treatment / all	0 / 23	0 / 34	0 / 57
<b>Disuse syndrome</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Euthanasia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Fatigue</b>			
subjects affected / exposed	4 / 2402 (0.17%)	4 / 2419 (0.17%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gait disturbance</b>			

subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	5 / 2402 (0.21%)	9 / 2419 (0.37%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	0 / 6	1 / 9	1 / 15
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 6
Hyperthermia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ill-defined disorder			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired self-care			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site haemorrhage			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lithiasis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Malaise</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	1 / 2	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mass</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Medical device discomfort</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Multiple organ dysfunction syndrome</b>			
subjects affected / exposed	7 / 2402 (0.29%)	10 / 2419 (0.41%)	17 / 4821 (0.35%)
occurrences causally related to treatment / all	0 / 7	0 / 10	0 / 17
deaths causally related to treatment / all	0 / 7	0 / 9	0 / 16
<b>Necrosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Non-cardiac chest pain</b>			
subjects affected / exposed	37 / 2402 (1.54%)	42 / 2419 (1.74%)	79 / 4821 (1.64%)
occurrences causally related to treatment / all	0 / 51	0 / 51	0 / 102
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oedema</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oedema peripheral</b>			
subjects affected / exposed	12 / 2402 (0.50%)	6 / 2419 (0.25%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 12	0 / 6	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pain</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Peripheral swelling</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyrexia</b>			
subjects affected / exposed	13 / 2402 (0.54%)	8 / 2419 (0.33%)	21 / 4821 (0.44%)
occurrences causally related to treatment / all	0 / 14	0 / 10	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Stenosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sudden cardiac death</b>			
subjects affected / exposed	16 / 2402 (0.67%)	15 / 2419 (0.62%)	31 / 4821 (0.64%)
occurrences causally related to treatment / all	1 / 16	0 / 15	1 / 31
deaths causally related to treatment / all	1 / 16	0 / 15	1 / 31
<b>Sudden death</b>			
subjects affected / exposed	22 / 2402 (0.92%)	21 / 2419 (0.87%)	43 / 4821 (0.89%)
occurrences causally related to treatment / all	1 / 22	0 / 21	1 / 43
deaths causally related to treatment / all	1 / 22	0 / 21	1 / 43
<b>Surgical failure</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	5 / 2402 (0.21%)	1 / 2419 (0.04%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Treatment noncompliance			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer haemorrhage			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Unevaluable event			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent stenosis			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Drug hypersensitivity</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Food allergy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sarcoidosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Social circumstances</b>			
<b>Immobile</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Living in residential institution</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Reproductive system and breast disorders</b>			
<b>Adenomyosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	5 / 2402 (0.21%)	8 / 2419 (0.33%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 5	0 / 8	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Breast calcifications			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cyst			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast mass			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical dysplasia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical polyp			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial thickening			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile dysfunction			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic haemorrhage			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal inflammation			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spermatocele			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	14 / 2402 (0.58%)	12 / 2419 (0.50%)	26 / 4821 (0.54%)
occurrences causally related to treatment / all	0 / 15	0 / 13	0 / 28
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 4
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	24 / 2402 (1.00%)	20 / 2419 (0.83%)	44 / 4821 (0.91%)
occurrences causally related to treatment / all	0 / 28	0 / 22	0 / 50
deaths causally related to treatment / all	0 / 9	0 / 7	0 / 16
Aspiration			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Asthma			

subjects affected / exposed	10 / 2402 (0.42%)	9 / 2419 (0.37%)	19 / 4821 (0.39%)
occurrences causally related to treatment / all	0 / 14	0 / 10	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Atelectasis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchial hyperreactivity</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Bronchial obstruction</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchiectasis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Bronchitis chronic</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchospasm</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Chronic obstructive pulmonary disease</b>			
subjects affected / exposed	67 / 2402 (2.79%)	42 / 2419 (1.74%)	109 / 4821 (2.26%)
occurrences causally related to treatment / all	1 / 92	0 / 65	1 / 157
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 5
<b>Chronic respiratory failure</b>			

subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Cough</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Dyspnoea</b>			
subjects affected / exposed	64 / 2402 (2.66%)	42 / 2419 (1.74%)	106 / 4821 (2.20%)
occurrences causally related to treatment / all	2 / 75	0 / 50	2 / 125
deaths causally related to treatment / all	0 / 6	0 / 1	0 / 7
<b>Dyspnoea at rest</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dyspnoea exertional</b>			
subjects affected / exposed	5 / 2402 (0.21%)	4 / 2419 (0.17%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Emphysema</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Epistaxis</b>			
subjects affected / exposed	4 / 2402 (0.17%)	4 / 2419 (0.17%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemoptysis</b>			
subjects affected / exposed	5 / 2402 (0.21%)	2 / 2419 (0.08%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Haemothorax</b>			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hydrothorax</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypercapnia</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Hypoventilation</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoxia</b>			
subjects affected / exposed	6 / 2402 (0.25%)	2 / 2419 (0.08%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Interstitial lung disease</b>			
subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
<b>Laryngeal haemorrhage</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Laryngeal oedema</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Laryngospasm</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal mass			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthopnoea			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal haemorrhage			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pickwickian syndrome			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pleural effusion</b>			
subjects affected / exposed	15 / 2402 (0.62%)	17 / 2419 (0.70%)	32 / 4821 (0.66%)
occurrences causally related to treatment / all	0 / 17	0 / 23	0 / 40
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Pleurisy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Pneumonia aspiration</b>			
subjects affected / exposed	11 / 2402 (0.46%)	7 / 2419 (0.29%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 11	0 / 8	0 / 19
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 4
<b>Pneumonitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumothorax</b>			
subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Presbyphonia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary alveolar haemorrhage</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary arterial hypertension</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary congestion</b>			
subjects affected / exposed	5 / 2402 (0.21%)	0 / 2419 (0.00%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary embolism</b>			
subjects affected / exposed	17 / 2402 (0.71%)	16 / 2419 (0.66%)	33 / 4821 (0.68%)
occurrences causally related to treatment / all	0 / 17	0 / 17	0 / 34
deaths causally related to treatment / all	0 / 4	0 / 4	0 / 8
<b>Pulmonary eosinophilia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary fibrosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
<b>Pulmonary hypertension</b>			
subjects affected / exposed	9 / 2402 (0.37%)	4 / 2419 (0.17%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 10	0 / 5	0 / 15
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Pulmonary mass</b>			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary oedema</b>			
subjects affected / exposed	16 / 2402 (0.67%)	7 / 2419 (0.29%)	23 / 4821 (0.48%)
occurrences causally related to treatment / all	0 / 17	0 / 7	0 / 24
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Respiratory acidosis</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory arrest</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Respiratory depression</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory distress</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Respiratory failure</b>			
subjects affected / exposed	32 / 2402 (1.33%)	29 / 2419 (1.20%)	61 / 4821 (1.27%)
occurrences causally related to treatment / all	0 / 39	0 / 32	0 / 71
deaths causally related to treatment / all	0 / 13	0 / 13	0 / 26
<b>Respiratory tract congestion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	5 / 2402 (0.21%)	4 / 2419 (0.17%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Status asthmaticus</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tracheal stenosis</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder with mixed anxiety and depressed mood			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Alcoholism			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			

subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
<b>Anxiety disorder</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Behaviour disorder</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Completed suicide</b>			
subjects affected / exposed	2 / 2402 (0.08%)	4 / 2419 (0.17%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 6
<b>Confusional state</b>			
subjects affected / exposed	7 / 2402 (0.29%)	6 / 2419 (0.25%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	1 / 7	2 / 8	3 / 15
deaths causally related to treatment / all	0 / 1	1 / 1	1 / 2
<b>Delirium</b>			
subjects affected / exposed	11 / 2402 (0.46%)	7 / 2419 (0.29%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 11	0 / 8	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Delirium febrile</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Delusion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Depressed mood</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Depression			
subjects affected / exposed	7 / 2402 (0.29%)	6 / 2419 (0.25%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	1 / 11	0 / 7	1 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Hallucination			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder due to a general medical condition			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	5 / 2402 (0.21%)	3 / 2419 (0.12%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	1 / 8	0 / 3	1 / 11
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Organic brain syndrome			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Paranoia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Personality disorder</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Somatic symptom disorder</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Suicidal ideation</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Suicide attempt</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Product issues</b>			
<b>Device battery issue</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Device breakage</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Device damage</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device defective			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	1 / 4	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device leakage			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device loosening			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lead dislodgement			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatobiliary disorders</b>			
<b>Bile duct obstruction</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bile duct stenosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bile duct stone</b>			
subjects affected / exposed	4 / 2402 (0.17%)	5 / 2419 (0.21%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Biliary colic</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Biliary dyskinesia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholangitis</b>			
subjects affected / exposed	4 / 2402 (0.17%)	4 / 2419 (0.17%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholangitis acute</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Cholecystitis</b>			

subjects affected / exposed	11 / 2402 (0.46%)	14 / 2419 (0.58%)	25 / 4821 (0.52%)
occurrences causally related to treatment / all	1 / 11	0 / 15	1 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholecystitis acute</b>			
subjects affected / exposed	9 / 2402 (0.37%)	8 / 2419 (0.33%)	17 / 4821 (0.35%)
occurrences causally related to treatment / all	0 / 10	0 / 8	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Cholecystitis chronic</b>			
subjects affected / exposed	2 / 2402 (0.08%)	5 / 2419 (0.21%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholelithiasis</b>			
subjects affected / exposed	19 / 2402 (0.79%)	17 / 2419 (0.70%)	36 / 4821 (0.75%)
occurrences causally related to treatment / all	2 / 19	0 / 19	2 / 38
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Cholelithiasis migration</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholestasis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Chronic hepatic failure</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cirrhosis alcoholic</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cryptogenic cirrhosis</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder disorder			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Gallbladder rupture			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemobilia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	6 / 2402 (0.25%)	4 / 2419 (0.17%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 9	0 / 4	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Hepatic cyst			
subjects affected / exposed	6 / 2402 (0.25%)	5 / 2419 (0.21%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Hepatic function abnormal			
subjects affected / exposed	5 / 2402 (0.21%)	5 / 2419 (0.21%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hepatic lesion			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatic mass</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatic steatosis</b>			
subjects affected / exposed	10 / 2402 (0.42%)	10 / 2419 (0.41%)	20 / 4821 (0.41%)
occurrences causally related to treatment / all	0 / 10	0 / 10	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatitis acute</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatobiliary disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatocellular injury</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hepatomegaly</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Hepatorenal syndrome</b>			

subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Hepatosplenomegaly</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Jaundice</b>			
subjects affected / exposed	5 / 2402 (0.21%)	8 / 2419 (0.33%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 5	0 / 8	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Jaundice cholestatic</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Liver disorder</b>			
subjects affected / exposed	4 / 2402 (0.17%)	1 / 2419 (0.04%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Liver injury</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nonalcoholic fatty liver disease</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Portal hypertension</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	1 / 2	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Portal vein thrombosis</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Primary biliary cholangitis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Steatohepatitis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation drug level above therapeutic			
subjects affected / exposed	4 / 2402 (0.17%)	2 / 2419 (0.08%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 2402 (0.08%)	4 / 2419 (0.17%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	1 / 2	0 / 4	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding time abnormal			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	4 / 2402 (0.17%)	1 / 2419 (0.04%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	3 / 4	0 / 1	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose abnormal			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose decreased			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose fluctuation			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose increased			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood osmolarity decreased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure decreased			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood sodium decreased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood urea increased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain natriuretic peptide increased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac output decreased			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulation time prolonged			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram repolarisation abnormality			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular filtration rate decreased			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	2 / 3	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate decreased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate irregular			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	6 / 2402 (0.25%)	7 / 2419 (0.29%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 7	1 / 7	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory marker increased			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Influenza virus test positive			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Lipase increased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precancerous cells present			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulse absent			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory rate increased			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin T increased			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	4 / 2402 (0.17%)	0 / 2419 (0.00%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	1 / 4	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
Ventilation/perfusion scan abnormal			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual field tests abnormal			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Injury, poisoning and procedural complications</b>			
<b>Abdominal injury</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Accident</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Accidental overdose</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Acetabulum fracture</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Alcohol poisoning</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaemia postoperative</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anastomotic leak</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anastomotic ulcer</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Animal bite</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Ankle fracture</b>			
subjects affected / exposed	4 / 2402 (0.17%)	7 / 2419 (0.29%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arterial bypass occlusion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arteriovenous fistula thrombosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Avulsion fracture</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bone contusion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Brain herniation</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Carbon monoxide poisoning</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac function disturbance postoperative			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cervical vertebral fracture			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Comminuted fracture			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complications of transplanted kidney			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary bypass stenosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Cystitis radiation			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extra dose administered			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	26 / 2402 (1.08%)	33 / 2419 (1.36%)	59 / 4821 (1.22%)
occurrences causally related to treatment / all	2 / 29	3 / 37	5 / 66
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
Femoral neck fracture			
subjects affected / exposed	8 / 2402 (0.33%)	5 / 2419 (0.21%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Femur fracture			
subjects affected / exposed	20 / 2402 (0.83%)	11 / 2419 (0.45%)	31 / 4821 (0.64%)
occurrences causally related to treatment / all	0 / 21	0 / 11	0 / 32
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Foot fracture			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			

subjects affected / exposed	6 / 2402 (0.25%)	5 / 2419 (0.21%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hip fracture			
subjects affected / exposed	14 / 2402 (0.58%)	13 / 2419 (0.54%)	27 / 4821 (0.56%)
occurrences causally related to treatment / all	0 / 14	0 / 14	0 / 28
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Humerus fracture			
subjects affected / exposed	7 / 2402 (0.29%)	5 / 2419 (0.21%)	12 / 4821 (0.25%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypobarism			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haematoma			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Joint dislocation			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Meniscus injury			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Muscle strain			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve root injury cervical			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Overdose			
subjects affected / exposed	2 / 2402 (0.08%)	4 / 2419 (0.17%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Patella fracture			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Periprosthetic fracture			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			

subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural myocardial infarction			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic pain			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative hypotension			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative respiratory failure			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Postoperative wound complication			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural vomiting			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation proctitis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	1 / 2402 (0.04%)	7 / 2419 (0.29%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory fume inhalation disorder			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Rib fracture			
subjects affected / exposed	6 / 2402 (0.25%)	11 / 2419 (0.45%)	17 / 4821 (0.35%)
occurrences causally related to treatment / all	0 / 6	0 / 11	0 / 17
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Road traffic accident			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sedation complication			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Skin abrasion			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin laceration</b>			
subjects affected / exposed	2 / 2402 (0.08%)	6 / 2419 (0.25%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal compression fracture</b>			
subjects affected / exposed	8 / 2402 (0.33%)	3 / 2419 (0.12%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal fracture</b>			
subjects affected / exposed	2 / 2402 (0.08%)	6 / 2419 (0.25%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Splenic rupture</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Stomal hernia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Subdural haematoma</b>			
subjects affected / exposed	8 / 2402 (0.33%)	7 / 2419 (0.29%)	15 / 4821 (0.31%)
occurrences causally related to treatment / all	0 / 8	1 / 10	1 / 18
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 4
<b>Subdural haemorrhage</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tendon rupture</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	8 / 2402 (0.33%)	2 / 2419 (0.08%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Vascular graft occlusion			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm ruptured			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital coronary artery malformation			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital megaureter			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUMBAR syndrome			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery hypoplasia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	13 / 2402 (0.54%)	11 / 2419 (0.45%)	24 / 4821 (0.50%)
occurrences causally related to treatment / all	0 / 15	1 / 11	1 / 26
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Acute left ventricular failure			
subjects affected / exposed	15 / 2402 (0.62%)	14 / 2419 (0.58%)	29 / 4821 (0.60%)
occurrences causally related to treatment / all	0 / 19	0 / 22	0 / 41
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Acute myocardial infarction			

subjects affected / exposed	54 / 2402 (2.25%)	60 / 2419 (2.48%)	114 / 4821 (2.36%)
occurrences causally related to treatment / all	0 / 61	0 / 69	0 / 130
deaths causally related to treatment / all	0 / 9	0 / 8	0 / 17
<b>Adams-Stokes syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Angina pectoris</b>			
subjects affected / exposed	50 / 2402 (2.08%)	42 / 2419 (1.74%)	92 / 4821 (1.91%)
occurrences causally related to treatment / all	1 / 57	1 / 49	2 / 106
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 4
<b>Angina unstable</b>			
subjects affected / exposed	43 / 2402 (1.79%)	50 / 2419 (2.07%)	93 / 4821 (1.93%)
occurrences causally related to treatment / all	0 / 52	0 / 61	0 / 113
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aortic valve disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aortic valve incompetence</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Aortic valve stenosis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arrhythmia</b>			
subjects affected / exposed	4 / 2402 (0.17%)	4 / 2419 (0.17%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 4	1 / 4	1 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Arrhythmia supraventricular</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	4 / 2402 (0.17%)	4 / 2419 (0.17%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	145 / 2402 (6.04%)	162 / 2419 (6.70%)	307 / 4821 (6.37%)
occurrences causally related to treatment / all	4 / 196	8 / 220	12 / 416
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Atrial flutter			
subjects affected / exposed	23 / 2402 (0.96%)	31 / 2419 (1.28%)	54 / 4821 (1.12%)
occurrences causally related to treatment / all	1 / 27	2 / 38	3 / 65
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Atrial tachycardia			
subjects affected / exposed	2 / 2402 (0.08%)	7 / 2419 (0.29%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 9	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	4 / 2402 (0.17%)	6 / 2419 (0.25%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	11 / 2402 (0.46%)	8 / 2419 (0.33%)	19 / 4821 (0.39%)
occurrences causally related to treatment / all	0 / 11	0 / 8	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block first degree			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Bradycardia			
subjects affected / exposed	24 / 2402 (1.00%)	27 / 2419 (1.12%)	51 / 4821 (1.06%)
occurrences causally related to treatment / all	1 / 26	0 / 27	1 / 53
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Bundle branch block left			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac amyloidosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiac arrest			
subjects affected / exposed	30 / 2402 (1.25%)	17 / 2419 (0.70%)	47 / 4821 (0.97%)
occurrences causally related to treatment / all	0 / 30	1 / 17	1 / 47
deaths causally related to treatment / all	0 / 21	1 / 13	1 / 34
Cardiac asthma			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiac discomfort			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	380 / 2402 (15.82%)	340 / 2419 (14.06%)	720 / 4821 (14.93%)
occurrences causally related to treatment / all	15 / 652	5 / 529	20 / 1181
deaths causally related to treatment / all	1 / 49	0 / 41	1 / 90
Cardiac failure acute			
subjects affected / exposed	77 / 2402 (3.21%)	85 / 2419 (3.51%)	162 / 4821 (3.36%)
occurrences causally related to treatment / all	1 / 109	1 / 113	2 / 222
deaths causally related to treatment / all	0 / 7	0 / 10	0 / 17
Cardiac failure chronic			
subjects affected / exposed	30 / 2402 (1.25%)	26 / 2419 (1.07%)	56 / 4821 (1.16%)
occurrences causally related to treatment / all	1 / 47	4 / 38	5 / 85
deaths causally related to treatment / all	0 / 4	1 / 5	1 / 9
Cardiac failure congestive			
subjects affected / exposed	83 / 2402 (3.46%)	86 / 2419 (3.56%)	169 / 4821 (3.51%)
occurrences causally related to treatment / all	0 / 155	5 / 146	5 / 301
deaths causally related to treatment / all	0 / 5	0 / 13	0 / 18
Cardiac fibrillation			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac flutter			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac tamponade			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac valve disease			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ventricular disorder			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	13 / 2402 (0.54%)	15 / 2419 (0.62%)	28 / 4821 (0.58%)
occurrences causally related to treatment / all	0 / 13	0 / 15	0 / 28
deaths causally related to treatment / all	0 / 11	0 / 12	0 / 23
Cardiogenic shock			
subjects affected / exposed	6 / 2402 (0.25%)	12 / 2419 (0.50%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 6	1 / 12	1 / 18
deaths causally related to treatment / all	0 / 4	0 / 6	0 / 10
Cardiomegaly			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiopulmonary failure			
subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 5
Cardiorenal syndrome			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cardiovascular insufficiency			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Chronic left ventricular failure			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	27 / 2402 (1.12%)	24 / 2419 (0.99%)	51 / 4821 (1.06%)
occurrences causally related to treatment / all	0 / 30	1 / 25	1 / 55
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
Coronary artery occlusion			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	2 / 2402 (0.08%)	5 / 2419 (0.21%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			

subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Intracardiac mass</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Ischaemic cardiomyopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Left ventricular dysfunction</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Left ventricular failure</b>			
subjects affected / exposed	5 / 2402 (0.21%)	6 / 2419 (0.25%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Microvascular coronary artery disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mitral valve calcification</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mitral valve incompetence</b>			
subjects affected / exposed	8 / 2402 (0.33%)	7 / 2419 (0.29%)	15 / 4821 (0.31%)
occurrences causally related to treatment / all	0 / 10	1 / 7	1 / 17
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Mitral valve prolapse</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myocardial infarction</b>			
subjects affected / exposed	35 / 2402 (1.46%)	32 / 2419 (1.32%)	67 / 4821 (1.39%)
occurrences causally related to treatment / all	1 / 38	1 / 36	2 / 74
deaths causally related to treatment / all	1 / 13	0 / 11	1 / 24
<b>Myocardial ischaemia</b>			
subjects affected / exposed	11 / 2402 (0.46%)	7 / 2419 (0.29%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 11	0 / 7	0 / 18
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Myocardial rupture</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Myocarditis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
<b>Nodal rhythm</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Palpitations</b>			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pericardial effusion</b>			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pericarditis</b>			

subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis constrictive			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Right ventricular dysfunction			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Right ventricular failure			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinoatrial block			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrest			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	8 / 2402 (0.33%)	1 / 2419 (0.04%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			

subjects affected / exposed	12 / 2402 (0.50%)	18 / 2419 (0.74%)	30 / 4821 (0.62%)
occurrences causally related to treatment / all	0 / 12	0 / 18	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sinus tachycardia</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Stress cardiomyopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Supraventricular extrasystoles</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Supraventricular tachycardia</b>			
subjects affected / exposed	3 / 2402 (0.12%)	6 / 2419 (0.25%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 11	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Systolic dysfunction</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tachyarrhythmia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tachycardia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Torsade de pointes</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trifascicular block			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular dyssynchrony			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	5 / 2402 (0.21%)	4 / 2419 (0.17%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Ventricular tachycardia			
subjects affected / exposed	4 / 2402 (0.17%)	9 / 2419 (0.37%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Nervous system disorders			
Altered state of consciousness			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Amyotrophic lateral sclerosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aphasia</b>			
subjects affected / exposed	4 / 2402 (0.17%)	1 / 2419 (0.04%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Ataxia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Brain hypoxia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Brain injury</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Brain oedema</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Brain stem stroke</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Carotid artery aneurysm</b>			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Carotid artery disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Carotid artery stenosis</b>			
subjects affected / exposed	7 / 2402 (0.29%)	9 / 2419 (0.37%)	16 / 4821 (0.33%)
occurrences causally related to treatment / all	0 / 8	0 / 10	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Carpal tunnel syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Central nervous system lesion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cerebellar haematoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Cerebellar infarction</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cerebellar ischaemia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cerebral arteriosclerosis</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery embolism			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral cyst			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cerebral haemorrhage			
subjects affected / exposed	6 / 2402 (0.25%)	5 / 2419 (0.21%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 5
Cerebral infarction			
subjects affected / exposed	18 / 2402 (0.75%)	17 / 2419 (0.70%)	35 / 4821 (0.73%)
occurrences causally related to treatment / all	0 / 20	1 / 20	1 / 40
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Cerebral ischaemia			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	2 / 3	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral thrombosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	42 / 2402 (1.75%)	39 / 2419 (1.61%)	81 / 4821 (1.68%)
occurrences causally related to treatment / all	0 / 48	2 / 46	2 / 94
deaths causally related to treatment / all	0 / 8	1 / 10	1 / 18
<b>Cerebrovascular disorder</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cerebrovascular insufficiency</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cervical radiculopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cervicobrachial syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cognitive disorder</b>			
subjects affected / exposed	2 / 2402 (0.08%)	7 / 2419 (0.29%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 2	2 / 7	2 / 9
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Coma</b>			
subjects affected / exposed	4 / 2402 (0.17%)	1 / 2419 (0.04%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Dementia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Dementia Alzheimer's type</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Dementia with Lewy bodies</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Depressed level of consciousness</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetic ketoacidotic hyperglycaemic coma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetic neuropathy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dizziness</b>			
subjects affected / exposed	11 / 2402 (0.46%)	17 / 2419 (0.70%)	28 / 4821 (0.58%)
occurrences causally related to treatment / all	2 / 11	4 / 19	6 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dysarthria</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Embolic stroke</b>			
subjects affected / exposed	4 / 2402 (0.17%)	5 / 2419 (0.21%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Encephalopathy</b>			

subjects affected / exposed	6 / 2402 (0.25%)	1 / 2419 (0.04%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Epilepsy</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Facial paralysis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Generalised tonic-clonic seizure</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Guillain-Barre syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemorrhage intracranial</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Haemorrhagic cerebral infarction</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Haemorrhagic stroke</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Haemorrhagic transformation stroke</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Headache</b>			
subjects affected / exposed	10 / 2402 (0.42%)	3 / 2419 (0.12%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 11	0 / 3	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Hemiparesis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hemiplegia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Hepatic encephalopathy</b>			
subjects affected / exposed	5 / 2402 (0.21%)	1 / 2419 (0.04%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	1 / 8	0 / 1	1 / 9
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Hydrocephalus</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoaesthesia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoglycaemic coma</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoxic-ischaemic encephalopathy</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paralysis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Ischaemic stroke			
subjects affected / exposed	29 / 2402 (1.21%)	32 / 2419 (1.32%)	61 / 4821 (1.27%)
occurrences causally related to treatment / all	0 / 29	0 / 36	0 / 65
deaths causally related to treatment / all	0 / 5	0 / 4	0 / 9
Lacunar infarction			
subjects affected / exposed	2 / 2402 (0.08%)	4 / 2419 (0.17%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar stroke			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lethargy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Loss of consciousness</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	1 / 3	1 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Lumbar radiculopathy</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lumbosacral radiculopathy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Metabolic encephalopathy</b>			
subjects affected / exposed	3 / 2402 (0.12%)	6 / 2419 (0.25%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Migraine</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mixed dementia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Motor dysfunction</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Movement disorder</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Multiple system atrophy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myasthenia gravis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myasthenic syndrome</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myelopathy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myoclonus</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nervous system disorder</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Neuralgia</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neuropathy peripheral</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Normal pressure hydrocephalus</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Parkinson's disease</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Parkinsonism</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Peripheral sensorimotor neuropathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Polyneuropathy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Post herpetic neuralgia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Post stroke epilepsy</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudoradicular syndrome			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Resting tremor			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	4 / 2402 (0.17%)	4 / 2419 (0.17%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 2402 (0.08%)	6 / 2419 (0.25%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory disturbance			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Somnolence</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Speech disorder</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal cord compression</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal cord disorder</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spondylitic myelopathy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Status epilepticus</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Stroke in evolution</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Subarachnoid haemorrhage</b>			

subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Syncope</b>			
subjects affected / exposed	57 / 2402 (2.37%)	41 / 2419 (1.69%)	98 / 4821 (2.03%)
occurrences causally related to treatment / all	9 / 67	12 / 44	21 / 111
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Thalamus haemorrhage</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Thrombotic cerebral infarction</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Thrombotic stroke</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Toxic encephalopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Transient ischaemic attack</b>			
subjects affected / exposed	26 / 2402 (1.08%)	34 / 2419 (1.41%)	60 / 4821 (1.24%)
occurrences causally related to treatment / all	1 / 26	2 / 37	3 / 63
deaths causally related to treatment / all	0 / 0	1 / 2	1 / 2
<b>Tremor</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Trigeminal neuralgia</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unresponsive to stimuli			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Uraemic encephalopathy			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paresis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular parkinsonism			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	2 / 2402 (0.08%)	4 / 2419 (0.17%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo CNS origin			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Acquired haemophilia			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaemia</b>			
subjects affected / exposed	67 / 2402 (2.79%)	68 / 2419 (2.81%)	135 / 4821 (2.80%)
occurrences causally related to treatment / all	1 / 77	1 / 83	2 / 160
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Anaemia macrocytic</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaemia megaloblastic</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaemia vitamin B12 deficiency</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Autoimmune haemolytic anaemia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Blood loss anaemia</b>			
subjects affected / exposed	7 / 2402 (0.29%)	2 / 2419 (0.08%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Coagulopathy</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Disseminated intravascular coagulation</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hypercoagulation			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersplenism			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	6 / 2402 (0.25%)	5 / 2419 (0.21%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	6 / 2402 (0.25%)	1 / 2419 (0.04%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Leukopenia			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrogenic anaemia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Splenic infarction			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Splenitis			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 2402 (0.04%)	6 / 2419 (0.25%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Thrombocytosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden hearing loss			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinnitus			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	3 / 2402 (0.12%)	6 / 2419 (0.25%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	1 / 2402 (0.04%)	5 / 2419 (0.21%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular ischaemia			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Eye disorders</b>			
Amaurosis fugax			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	12 / 2402 (0.50%)	14 / 2419 (0.58%)	26 / 4821 (0.54%)
occurrences causally related to treatment / all	0 / 14	0 / 14	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract diabetic			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctival haemorrhage			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Entropion			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye pain			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			

subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Macular degeneration</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Macular fibrosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Maculopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Narrow anterior chamber angle</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neovascular age-related macular degeneration</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pterygium</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Retinal detachment</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Retinal haemorrhage</b>			

subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Retinal vein occlusion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vision blurred</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Visual acuity reduced</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vitreous haemorrhage</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal disorders</b>			
<b>Abdominal distension</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal hernia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal pain</b>			
subjects affected / exposed	8 / 2402 (0.33%)	6 / 2419 (0.25%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal pain lower</b>			

subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Abdominal wall haematoma			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal incontinence			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal mucocoele			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	9 / 2402 (0.37%)	8 / 2419 (0.33%)	17 / 4821 (0.35%)
occurrences causally related to treatment / all	1 / 12	0 / 13	1 / 25
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Chronic gastritis			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	3 / 2402 (0.12%)	5 / 2419 (0.21%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Colitis microscopic			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	6 / 2402 (0.25%)	2 / 2419 (0.08%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gastroenteropathy			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
Diarrhoea			
subjects affected / exposed	14 / 2402 (0.58%)	13 / 2419 (0.54%)	27 / 4821 (0.56%)
occurrences causally related to treatment / all	0 / 15	0 / 13	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dieulafoy's vascular malformation			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Diverticular perforation			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Diverticulum			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal polyp			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Faecaloma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Faeces discoloured</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Femoral hernia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric disorder</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric haemorrhage</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric polyps</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric ulcer</b>			
subjects affected / exposed	3 / 2402 (0.12%)	8 / 2419 (0.33%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastric ulcer haemorrhage</b>			

subjects affected / exposed	4 / 2402 (0.17%)	2 / 2419 (0.08%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastritis</b>			
subjects affected / exposed	7 / 2402 (0.29%)	3 / 2419 (0.12%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastritis erosive</b>			
subjects affected / exposed	7 / 2402 (0.29%)	1 / 2419 (0.04%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastritis haemorrhagic</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal haemorrhage</b>			
subjects affected / exposed	32 / 2402 (1.33%)	29 / 2419 (1.20%)	61 / 4821 (1.27%)
occurrences causally related to treatment / all	1 / 36	0 / 31	1 / 67
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 4
<b>Gastrointestinal perforation</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Gastrointestinal polyp haemorrhage</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal ulcer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastrointestinal ulcer haemorrhage</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal wall thickening			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Haematochezia			
subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	3 / 2402 (0.12%)	5 / 2419 (0.21%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Ileus paralytic			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Impaired gastric emptying			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
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 inguinal hernia			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	13 / 2402 (0.54%)	10 / 2419 (0.41%)	23 / 4821 (0.48%)
occurrences causally related to treatment / all	0 / 14	0 / 10	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			

subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intestinal infarction</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Intestinal ischaemia</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Intestinal obstruction</b>			
subjects affected / exposed	5 / 2402 (0.21%)	5 / 2419 (0.21%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Intestinal perforation</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Intestinal polyp</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intestinal strangulation</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intra-abdominal haematoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intra-abdominal haemorrhage</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Irritable bowel syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Large intestinal obstruction</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Large intestine perforation</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Large intestine polyp</b>			
subjects affected / exposed	4 / 2402 (0.17%)	5 / 2419 (0.21%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lower gastrointestinal haemorrhage</b>			
subjects affected / exposed	6 / 2402 (0.25%)	1 / 2419 (0.04%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Mallory-Weiss syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Melaena</b>			
subjects affected / exposed	6 / 2402 (0.25%)	7 / 2419 (0.29%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Mouth haemorrhage</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nausea</b>			
subjects affected / exposed	5 / 2402 (0.21%)	12 / 2419 (0.50%)	17 / 4821 (0.35%)
occurrences causally related to treatment / all	0 / 6	0 / 15	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Obstructive pancreatitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal haemorrhage</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal perforation</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Oesophageal ulcer</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis acute</b>			
subjects affected / exposed	9 / 2402 (0.37%)	5 / 2419 (0.21%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	1 / 10	0 / 6	1 / 16
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
<b>Pancreatitis chronic</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis necrotising</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pancreatitis relapsing</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Peptic ulcer haemorrhage</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Peritoneal haemorrhage</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Portal hypertensive gastropathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Proctitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rectal haemorrhage</b>			
subjects affected / exposed	4 / 2402 (0.17%)	9 / 2419 (0.37%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 4	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rectal polyp</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland calculus			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	5 / 2402 (0.21%)	7 / 2419 (0.29%)	12 / 4821 (0.25%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toothache			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			

subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	11 / 2402 (0.46%)	7 / 2419 (0.29%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 11	0 / 8	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Varices oesophageal			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	11 / 2402 (0.46%)	9 / 2419 (0.37%)	20 / 4821 (0.41%)
occurrences causally related to treatment / all	1 / 12	0 / 9	1 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 2402 (0.04%)	5 / 2419 (0.21%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 1	4 / 5	4 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blister			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Butterfly rash			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Dermatitis			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	5 / 2402 (0.21%)	2 / 2419 (0.08%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic wound			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema asteatotic			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage subcutaneous			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
Hyperhidrosis			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intertrigo			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic skin ulcer			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurodermatitis			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purpura			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pruritic			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinophyma			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin lesion</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin ulcer</b>			
subjects affected / exposed	3 / 2402 (0.12%)	5 / 2419 (0.21%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Subcutaneous emphysema</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Urticaria</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Vasculitic ulcer</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal and urinary disorders</b>			
<b>Acute kidney injury</b>			
subjects affected / exposed	110 / 2402 (4.58%)	90 / 2419 (3.72%)	200 / 4821 (4.15%)
occurrences causally related to treatment / all	47 / 142	29 / 110	76 / 252
deaths causally related to treatment / all	2 / 12	2 / 9	4 / 21
<b>Anuria</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Azotaemia</b>			

subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Bladder diverticulum			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neck obstruction			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder prolapse			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urethral			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	14 / 2402 (0.58%)	13 / 2419 (0.54%)	27 / 4821 (0.56%)
occurrences causally related to treatment / all	5 / 16	3 / 13	8 / 29
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>End stage renal disease</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Glomerulonephritis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Glomerulonephropathy</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haematuria</b>			
subjects affected / exposed	8 / 2402 (0.33%)	5 / 2419 (0.21%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 9	0 / 5	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemorrhage urinary tract</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hydronephrosis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nephrolithiasis</b>			
subjects affected / exposed	5 / 2402 (0.21%)	3 / 2419 (0.12%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nephropathy toxic</b>			

subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Nephrotic syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oliguria</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Prerenal failure</b>			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	1 / 3	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Proteinuria</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal artery stenosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal colic</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal cyst</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal disorder</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal failure</b>			
subjects affected / exposed	29 / 2402 (1.21%)	31 / 2419 (1.28%)	60 / 4821 (1.24%)
occurrences causally related to treatment / all	5 / 33	10 / 36	15 / 69
deaths causally related to treatment / all	0 / 5	0 / 5	0 / 10
<b>Renal impairment</b>			
subjects affected / exposed	48 / 2402 (2.00%)	24 / 2419 (0.99%)	72 / 4821 (1.49%)
occurrences causally related to treatment / all	17 / 53	11 / 25	28 / 78
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Renal infarct</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
<b>Renal injury</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal mass</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal pain</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal tubular necrosis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Renal vein stenosis</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Ureterolithiasis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	8 / 2402 (0.33%)	8 / 2419 (0.33%)	16 / 4821 (0.33%)
occurrences causally related to treatment / all	0 / 8	0 / 9	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercorticism			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperparathyroidism</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperthyroidism</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypothyroidism</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Inappropriate antidiuretic hormone secretion</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Parathyroid hyperplasia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Acquired claw toe</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arthralgia</b>			
subjects affected / exposed	7 / 2402 (0.29%)	4 / 2419 (0.17%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 8	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arthritis</b>			

subjects affected / exposed	3 / 2402 (0.12%)	5 / 2419 (0.21%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Back pain</b>			
subjects affected / exposed	11 / 2402 (0.46%)	11 / 2419 (0.45%)	22 / 4821 (0.46%)
occurrences causally related to treatment / all	0 / 12	0 / 12	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bursitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>CREST syndrome</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Chest wall haematoma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Chondrocalcinosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Costochondritis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dactylitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dupuytren's contracture</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Exostosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fibromyalgia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Flank pain</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Foot deformity</b>			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gouty arthritis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	3 / 2419 (0.12%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Haemarthrosis</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intervertebral disc degeneration</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intervertebral disc disorder</b>			

subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	5 / 2402 (0.21%)	9 / 2419 (0.37%)	14 / 4821 (0.29%)
occurrences causally related to treatment / all	0 / 5	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphosis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	5 / 2402 (0.21%)	4 / 2419 (0.17%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	4 / 2402 (0.17%)	3 / 2419 (0.12%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			

subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Musculoskeletal pain</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myalgia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myositis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Myositis ossificans</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Neck pain</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteitis deformans</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteoarthritis</b>			

subjects affected / exposed	28 / 2402 (1.17%)	31 / 2419 (1.28%)	59 / 4821 (1.22%)
occurrences causally related to treatment / all	0 / 31	0 / 39	0 / 70
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteochondrosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteonecrosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteoporosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pain in extremity</b>			
subjects affected / exposed	6 / 2402 (0.25%)	2 / 2419 (0.08%)	8 / 4821 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pathological fracture</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Periarthritis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Periostitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Polymyalgia rheumatica</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pseudarthrosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rheumatoid arthritis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Rotator cuff syndrome</b>			
subjects affected / exposed	3 / 2402 (0.12%)	6 / 2419 (0.25%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Scleroderma</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Spinal osteoarthritis</b>			
subjects affected / exposed	4 / 2402 (0.17%)	6 / 2419 (0.25%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal pain</b>			
subjects affected / exposed	6 / 2402 (0.25%)	3 / 2419 (0.12%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spinal stenosis</b>			
subjects affected / exposed	6 / 2402 (0.25%)	5 / 2419 (0.21%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Spondylolisthesis</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Synovial cyst</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Tenosynovitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
<b>Abdominal sepsis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abdominal wall abscess</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess jaw</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess limb</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess neck</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Abscess oral</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Acinetobacter bacteraemia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Acute endocarditis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Amoebiasis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
<b>Anal abscess</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Appendicitis</b>			
subjects affected / exposed	4 / 2402 (0.17%)	2 / 2419 (0.08%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Arthritis bacterial</b>			
subjects affected / exposed	6 / 2402 (0.25%)	3 / 2419 (0.12%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arthritis infective</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aspergillus infection</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Bacteraemia</b>			
subjects affected / exposed	7 / 2402 (0.29%)	6 / 2419 (0.25%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 9	0 / 7	0 / 16
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 2
<b>Bacterial disease carrier</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacterial infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacterial rhinitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacterial sepsis</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Beta haemolytic streptococcal infection</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Biliary sepsis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Biliary tract infection</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bone abscess</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchiolitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bronchitis</b>			
subjects affected / exposed	41 / 2402 (1.71%)	32 / 2419 (1.32%)	73 / 4821 (1.51%)
occurrences causally related to treatment / all	0 / 50	0 / 39	0 / 89
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
<b>Bronchitis viral</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Campylobacter infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cellulitis</b>			
subjects affected / exposed	25 / 2402 (1.04%)	30 / 2419 (1.24%)	55 / 4821 (1.14%)
occurrences causally related to treatment / all	0 / 35	0 / 38	0 / 73
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Chest wall abscess</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Cholangitis infective</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Chronic sinusitis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	3 / 2402 (0.12%)	6 / 2419 (0.25%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Clostridium difficile infection			
subjects affected / exposed	2 / 2402 (0.08%)	3 / 2419 (0.12%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis bacterial			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis escherichia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gangrene			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	9 / 2402 (0.37%)	3 / 2419 (0.12%)	12 / 4821 (0.25%)
occurrences causally related to treatment / all	0 / 10	0 / 3	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Eczema infected</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Embolic pneumonia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Endocarditis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
<b>Enteritis infectious</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Enterococcal bacteraemia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Enterococcal sepsis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Epididymitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Epiglottitis</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Erysipelas</b>			
subjects affected / exposed	7 / 2402 (0.29%)	11 / 2419 (0.45%)	18 / 4821 (0.37%)
occurrences causally related to treatment / all	0 / 8	0 / 15	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Escherichia bacteraemia</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Escherichia sepsis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Escherichia urinary tract infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gangrene</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Gastroenteritis</b>			
subjects affected / exposed	16 / 2402 (0.67%)	21 / 2419 (0.87%)	37 / 4821 (0.77%)
occurrences causally related to treatment / all	0 / 16	0 / 21	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Gastroenteritis bacterial</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gastroenteritis clostridial</b>			

subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital herpes zoster			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	4 / 2402 (0.17%)	2 / 2419 (0.08%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hordeolum			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Human anaplasmosis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	4 / 2402 (0.17%)	2 / 2419 (0.08%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	3 / 2402 (0.12%)	1 / 2419 (0.04%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of bronchiectasis			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Influenza</b>			
subjects affected / exposed	11 / 2402 (0.46%)	16 / 2419 (0.66%)	27 / 4821 (0.56%)
occurrences causally related to treatment / all	0 / 11	0 / 16	0 / 27
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
<b>Intervertebral discitis</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intestinal sepsis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Intracranial infection</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Klebsiella sepsis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Labyrinthitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Laryngitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Liver abscess</b>			

subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	5 / 2402 (0.21%)	4 / 2419 (0.17%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lower respiratory tract infection			
subjects affected / exposed	12 / 2402 (0.50%)	11 / 2419 (0.45%)	23 / 4821 (0.48%)
occurrences causally related to treatment / all	0 / 14	0 / 11	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
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 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	11 / 2402 (0.46%)	12 / 2419 (0.50%)	23 / 4821 (0.48%)
occurrences causally related to treatment / all	0 / 12	0 / 13	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lymphangitis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinitis			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Medical device site infection			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Meningitis enterococcal</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nasopharyngitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Necrotising fasciitis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nosocomial infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oesophageal candidiasis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Ophthalmic herpes zoster</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oral candidiasis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Oral herpes</b>			

subjects affected / exposed	0 / 2402 (0.00%)	2 / 2419 (0.08%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Orchitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Osteomyelitis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	7 / 2419 (0.29%)	10 / 4821 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Otitis media</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pelvic abscess</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Periodontitis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Peritonitis</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Peritonitis bacterial</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pharyngitis</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumococcal sepsis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Pneumonia</b>			
subjects affected / exposed	178 / 2402 (7.41%)	162 / 2419 (6.70%)	340 / 4821 (7.05%)
occurrences causally related to treatment / all	0 / 212	0 / 197	0 / 409
deaths causally related to treatment / all	0 / 24	0 / 23	0 / 47
<b>Pneumonia bacterial</b>			
subjects affected / exposed	5 / 2402 (0.21%)	4 / 2419 (0.17%)	9 / 4821 (0.19%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonia influenzal</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Pneumonia mycoplasmal</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonia pneumococcal</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonia respiratory syncytial viral</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonia streptococcal</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pneumonia viral</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Post procedural infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Postoperative wound infection</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	1 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pseudomembranous colitis</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary sepsis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pulmonary tuberculosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Pyelonephritis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Pyelonephritis acute</b>			

subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory moniliasis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	21 / 2402 (0.87%)	19 / 2419 (0.79%)	40 / 4821 (0.83%)
occurrences causally related to treatment / all	0 / 25	0 / 21	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 3
Respiratory tract infection bacterial			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Respiratory tract infection viral</b>			
subjects affected / exposed	2 / 2402 (0.08%)	1 / 2419 (0.04%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Salmonellosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Sepsis</b>			
subjects affected / exposed	37 / 2402 (1.54%)	34 / 2419 (1.41%)	71 / 4821 (1.47%)
occurrences causally related to treatment / all	1 / 44	0 / 41	1 / 85
deaths causally related to treatment / all	0 / 9	0 / 12	0 / 21
<b>Septic encephalopathy</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Septic necrosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Septic shock</b>			
subjects affected / exposed	16 / 2402 (0.67%)	21 / 2419 (0.87%)	37 / 4821 (0.77%)
occurrences causally related to treatment / all	0 / 17	0 / 23	0 / 40
deaths causally related to treatment / all	0 / 10	0 / 10	0 / 20
<b>Severe acute respiratory syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Shunt infection</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
<b>Skin bacterial infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Skin infection</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Soft tissue infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Staphylococcal bacteraemia</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Staphylococcal infection</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Staphylococcal sepsis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Streptococcal bacteraemia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Streptococcal sepsis</b>			

subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syphilis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (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
Tuberculous pleurisy			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubo-ovarian abscess			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	6 / 2402 (0.25%)	5 / 2419 (0.21%)	11 / 4821 (0.23%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethritis			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	68 / 2402 (2.83%)	54 / 2419 (2.23%)	122 / 4821 (2.53%)
occurrences causally related to treatment / all	0 / 76	0 / 68	0 / 144
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Urosepsis			
subjects affected / exposed	14 / 2402 (0.58%)	11 / 2419 (0.45%)	25 / 4821 (0.52%)
occurrences causally related to treatment / all	0 / 14	0 / 12	0 / 26
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 4
Vestibular neuronitis			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound abscess			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	3 / 2402 (0.12%)	2 / 2419 (0.08%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			

subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
Cardiometabolic syndrome			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Decreased appetite			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Dehydration			
subjects affected / exposed	26 / 2402 (1.08%)	18 / 2419 (0.74%)	44 / 4821 (0.91%)
occurrences causally related to treatment / all	1 / 30	1 / 18	2 / 48
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 3
Diabetes mellitus			
subjects affected / exposed	8 / 2402 (0.33%)	9 / 2419 (0.37%)	17 / 4821 (0.35%)
occurrences causally related to treatment / all	0 / 9	0 / 9	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Diabetes mellitus inadequate control			
subjects affected / exposed	3 / 2402 (0.12%)	4 / 2419 (0.17%)	7 / 4821 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic complication			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Diabetic ketoacidosis			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			

subjects affected / exposed	9 / 2402 (0.37%)	3 / 2419 (0.12%)	12 / 4821 (0.25%)
occurrences causally related to treatment / all	1 / 11	0 / 3	1 / 14
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
<b>Electrolyte imbalance</b>			
subjects affected / exposed	2 / 2402 (0.08%)	0 / 2419 (0.00%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Failure to thrive</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fluid overload</b>			
subjects affected / exposed	8 / 2402 (0.33%)	8 / 2419 (0.33%)	16 / 4821 (0.33%)
occurrences causally related to treatment / all	1 / 8	1 / 11	2 / 19
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Fluid retention</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Folate deficiency</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Gout</b>			
subjects affected / exposed	11 / 2402 (0.46%)	5 / 2419 (0.21%)	16 / 4821 (0.33%)
occurrences causally related to treatment / all	1 / 11	0 / 5	1 / 16
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Haemochromatosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperammonaemia</b>			

subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypercalcaemia</b>			
subjects affected / exposed	2 / 2402 (0.08%)	2 / 2419 (0.08%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Hypercholesterolaemia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	0 / 2419 (0.00%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperglycaemia</b>			
subjects affected / exposed	16 / 2402 (0.67%)	10 / 2419 (0.41%)	26 / 4821 (0.54%)
occurrences causally related to treatment / all	0 / 18	0 / 15	0 / 33
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Hyperglycaemic hyperosmolar nonketotic syndrome</b>			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperkalaemia</b>			
subjects affected / exposed	42 / 2402 (1.75%)	19 / 2419 (0.79%)	61 / 4821 (1.27%)
occurrences causally related to treatment / all	28 / 51	6 / 21	34 / 72
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 3
<b>Hypernatraemia</b>			
subjects affected / exposed	0 / 2402 (0.00%)	3 / 2419 (0.12%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hyperuricaemia</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hypoalbuminaemia</b>			

subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	6 / 2402 (0.25%)	20 / 2419 (0.83%)	26 / 4821 (0.54%)
occurrences causally related to treatment / all	0 / 6	0 / 20	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hypokalaemia			
subjects affected / exposed	14 / 2402 (0.58%)	8 / 2419 (0.33%)	22 / 4821 (0.46%)
occurrences causally related to treatment / all	1 / 15	0 / 9	1 / 24
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Hypomagnesaemia			
subjects affected / exposed	1 / 2402 (0.04%)	2 / 2419 (0.08%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	17 / 2402 (0.71%)	17 / 2419 (0.70%)	34 / 4821 (0.71%)
occurrences causally related to treatment / all	1 / 21	1 / 19	2 / 40
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoosmolar state			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	1 / 2402 (0.04%)	4 / 2419 (0.17%)	5 / 4821 (0.10%)
occurrences causally related to treatment / all	1 / 1	1 / 5	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Iron deficiency</b>			
subjects affected / exposed	4 / 2402 (0.17%)	0 / 2419 (0.00%)	4 / 4821 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Ketoacidosis</b>			
subjects affected / exposed	0 / 2402 (0.00%)	1 / 2419 (0.04%)	1 / 4821 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Lactic acidosis</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Malnutrition</b>			
subjects affected / exposed	3 / 2402 (0.12%)	0 / 2419 (0.00%)	3 / 4821 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Marasmus</b>			
subjects affected / exposed	1 / 2402 (0.04%)	1 / 2419 (0.04%)	2 / 4821 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
<b>Metabolic acidosis</b>			
subjects affected / exposed	3 / 2402 (0.12%)	3 / 2419 (0.12%)	6 / 4821 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
<b>Type 2 diabetes mellitus</b>			
subjects affected / exposed	8 / 2402 (0.33%)	5 / 2419 (0.21%)	13 / 4821 (0.27%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

<b>Non-serious adverse events</b>	Valsartan	LCZ696	All patients
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1995 / 2402 (83.06%)	2005 / 2419 (82.89%)	4000 / 4821 (82.97%)
<b>Vascular disorders</b>			
Hypertension			
subjects affected / exposed	314 / 2402 (13.07%)	225 / 2419 (9.30%)	539 / 4821 (11.18%)
occurrences (all)	403	264	667
Hypotension			
subjects affected / exposed	379 / 2402 (15.78%)	529 / 2419 (21.87%)	908 / 4821 (18.83%)
occurrences (all)	505	749	1254
<b>General disorders and administration site conditions</b>			
Asthenia			
subjects affected / exposed	58 / 2402 (2.41%)	60 / 2419 (2.48%)	118 / 4821 (2.45%)
occurrences (all)	62	71	133
Fatigue			
subjects affected / exposed	107 / 2402 (4.45%)	98 / 2419 (4.05%)	205 / 4821 (4.25%)
occurrences (all)	118	115	233
Non-cardiac chest pain			
subjects affected / exposed	92 / 2402 (3.83%)	98 / 2419 (4.05%)	190 / 4821 (3.94%)
occurrences (all)	103	115	218
Oedema peripheral			
subjects affected / exposed	183 / 2402 (7.62%)	166 / 2419 (6.86%)	349 / 4821 (7.24%)
occurrences (all)	221	202	423
Pyrexia			
subjects affected / exposed	54 / 2402 (2.25%)	59 / 2419 (2.44%)	113 / 4821 (2.34%)
occurrences (all)	65	76	141
<b>Respiratory, thoracic and mediastinal disorders</b>			
Chronic obstructive pulmonary disease			
subjects affected / exposed	68 / 2402 (2.83%)	57 / 2419 (2.36%)	125 / 4821 (2.59%)
occurrences (all)	86	69	155
Cough			

subjects affected / exposed occurrences (all)	146 / 2402 (6.08%) 174	188 / 2419 (7.77%) 234	334 / 4821 (6.93%) 408
Dyspnoea subjects affected / exposed occurrences (all)	236 / 2402 (9.83%) 291	217 / 2419 (8.97%) 262	453 / 4821 (9.40%) 553
Epistaxis subjects affected / exposed occurrences (all)	71 / 2402 (2.96%) 85	42 / 2419 (1.74%) 46	113 / 4821 (2.34%) 131
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	70 / 2402 (2.91%) 71	68 / 2419 (2.81%) 69	138 / 4821 (2.86%) 140
Insomnia subjects affected / exposed occurrences (all)	54 / 2402 (2.25%) 56	75 / 2419 (3.10%) 85	129 / 4821 (2.68%) 141
Investigations Blood creatinine increased subjects affected / exposed occurrences (all)	65 / 2402 (2.71%) 77	63 / 2419 (2.60%) 70	128 / 4821 (2.66%) 147
Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	93 / 2402 (3.87%) 116	85 / 2419 (3.51%) 101	178 / 4821 (3.69%) 217
Weight decreased subjects affected / exposed occurrences (all)	82 / 2402 (3.41%) 90	71 / 2419 (2.94%) 74	153 / 4821 (3.17%) 164
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	72 / 2402 (3.00%) 83	57 / 2419 (2.36%) 62	129 / 4821 (2.68%) 145
Fall subjects affected / exposed occurrences (all)	90 / 2402 (3.75%) 127	106 / 2419 (4.38%) 128	196 / 4821 (4.07%) 255
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	82 / 2402 (3.41%) 104	87 / 2419 (3.60%) 105	169 / 4821 (3.51%) 209

Atrial fibrillation subjects affected / exposed occurrences (all)	239 / 2402 (9.95%) 297	248 / 2419 (10.25%) 318	487 / 4821 (10.10%) 615
Bradycardia subjects affected / exposed occurrences (all)	85 / 2402 (3.54%) 90	53 / 2419 (2.19%) 57	138 / 4821 (2.86%) 147
Cardiac failure subjects affected / exposed occurrences (all)	269 / 2402 (11.20%) 376	225 / 2419 (9.30%) 304	494 / 4821 (10.25%) 680
Palpitations subjects affected / exposed occurrences (all)	56 / 2402 (2.33%) 66	62 / 2419 (2.56%) 70	118 / 4821 (2.45%) 136
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	192 / 2402 (7.99%) 213	229 / 2419 (9.47%) 298	421 / 4821 (8.73%) 511
Headache subjects affected / exposed occurrences (all)	126 / 2402 (5.25%) 139	114 / 2419 (4.71%) 131	240 / 4821 (4.98%) 270
Syncope subjects affected / exposed occurrences (all)	62 / 2402 (2.58%) 73	42 / 2419 (1.74%) 50	104 / 4821 (2.16%) 123
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	214 / 2402 (8.91%) 242	166 / 2419 (6.86%) 182	380 / 4821 (7.88%) 424
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	60 / 2402 (2.50%) 64	77 / 2419 (3.18%) 83	137 / 4821 (2.84%) 147
Eye disorders Cataract subjects affected / exposed occurrences (all)	70 / 2402 (2.91%) 83	84 / 2419 (3.47%) 105	154 / 4821 (3.19%) 188
Gastrointestinal disorders			

Abdominal pain subjects affected / exposed occurrences (all)	54 / 2402 (2.25%) 58	53 / 2419 (2.19%) 57	107 / 4821 (2.22%) 115
Constipation subjects affected / exposed occurrences (all)	86 / 2402 (3.58%) 93	100 / 2419 (4.13%) 108	186 / 4821 (3.86%) 201
Diarrhoea subjects affected / exposed occurrences (all)	180 / 2402 (7.49%) 212	177 / 2419 (7.32%) 214	357 / 4821 (7.41%) 426
Nausea subjects affected / exposed occurrences (all)	87 / 2402 (3.62%) 106	93 / 2419 (3.84%) 100	180 / 4821 (3.73%) 206
Vomiting subjects affected / exposed occurrences (all)	58 / 2402 (2.41%) 65	70 / 2419 (2.89%) 78	128 / 4821 (2.66%) 143
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	51 / 2402 (2.12%) 55	46 / 2419 (1.90%) 56	97 / 4821 (2.01%) 111
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	65 / 2402 (2.71%) 85	64 / 2419 (2.65%) 83	129 / 4821 (2.68%) 168
Chronic kidney disease subjects affected / exposed occurrences (all)	50 / 2402 (2.08%) 56	33 / 2419 (1.36%) 36	83 / 4821 (1.72%) 92
Haematuria subjects affected / exposed occurrences (all)	77 / 2402 (3.21%) 84	71 / 2419 (2.94%) 79	148 / 4821 (3.07%) 163
Renal failure subjects affected / exposed occurrences (all)	108 / 2402 (4.50%) 138	85 / 2419 (3.51%) 94	193 / 4821 (4.00%) 232
Renal impairment subjects affected / exposed occurrences (all)	331 / 2402 (13.78%) 414	287 / 2419 (11.86%) 347	618 / 4821 (12.82%) 761
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	153 / 2402 (6.37%)	152 / 2419 (6.28%)	305 / 4821 (6.33%)
occurrences (all)	186	178	364
Back pain			
subjects affected / exposed	170 / 2402 (7.08%)	149 / 2419 (6.16%)	319 / 4821 (6.62%)
occurrences (all)	191	166	357
Muscle spasms			
subjects affected / exposed	49 / 2402 (2.04%)	36 / 2419 (1.49%)	85 / 4821 (1.76%)
occurrences (all)	56	39	95
Musculoskeletal pain			
subjects affected / exposed	58 / 2402 (2.41%)	63 / 2419 (2.60%)	121 / 4821 (2.51%)
occurrences (all)	63	69	132
Osteoarthritis			
subjects affected / exposed	92 / 2402 (3.83%)	92 / 2419 (3.80%)	184 / 4821 (3.82%)
occurrences (all)	105	112	217
Pain in extremity			
subjects affected / exposed	75 / 2402 (3.12%)	81 / 2419 (3.35%)	156 / 4821 (3.24%)
occurrences (all)	84	87	171
Infections and infestations			
Bronchitis			
subjects affected / exposed	197 / 2402 (8.20%)	177 / 2419 (7.32%)	374 / 4821 (7.76%)
occurrences (all)	234	217	451
Cellulitis			
subjects affected / exposed	41 / 2402 (1.71%)	61 / 2419 (2.52%)	102 / 4821 (2.12%)
occurrences (all)	50	68	118
Influenza			
subjects affected / exposed	109 / 2402 (4.54%)	110 / 2419 (4.55%)	219 / 4821 (4.54%)
occurrences (all)	120	130	250
Nasopharyngitis			
subjects affected / exposed	177 / 2402 (7.37%)	207 / 2419 (8.56%)	384 / 4821 (7.97%)
occurrences (all)	243	272	515
Pneumonia			
subjects affected / exposed	97 / 2402 (4.04%)	100 / 2419 (4.13%)	197 / 4821 (4.09%)
occurrences (all)	114	105	219
Respiratory tract infection			

subjects affected / exposed occurrences (all)	60 / 2402 (2.50%) 74	48 / 2419 (1.98%) 54	108 / 4821 (2.24%) 128
Upper respiratory tract infection subjects affected / exposed occurrences (all)	139 / 2402 (5.79%) 185	145 / 2419 (5.99%) 197	284 / 4821 (5.89%) 382
Urinary tract infection subjects affected / exposed occurrences (all)	268 / 2402 (11.16%) 382	243 / 2419 (10.05%) 328	511 / 4821 (10.60%) 710
<b>Metabolism and nutrition disorders</b>			
Diabetes mellitus subjects affected / exposed occurrences (all)	62 / 2402 (2.58%) 65	52 / 2419 (2.15%) 57	114 / 4821 (2.36%) 122
Gout subjects affected / exposed occurrences (all)	88 / 2402 (3.66%) 106	76 / 2419 (3.14%) 100	164 / 4821 (3.40%) 206
Hyperkalaemia subjects affected / exposed occurrences (all)	298 / 2402 (12.41%) 423	238 / 2419 (9.84%) 325	536 / 4821 (11.12%) 748
Hyperuricaemia subjects affected / exposed occurrences (all)	75 / 2402 (3.12%) 83	62 / 2419 (2.56%) 65	137 / 4821 (2.84%) 148
Hypokalaemia subjects affected / exposed occurrences (all)	100 / 2402 (4.16%) 128	110 / 2419 (4.55%) 134	210 / 4821 (4.36%) 262

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 June 2014	The main purpose of this amendment was to increase the contraception period for women of child-bearing potential after being taken off study medication from 4 days to 7 days in exclusion criterion 33 in order to be consistent with the other study protocols from the LCZ696 clinical program and with the LCZ696 Investigators' Brochure. Updated TOPCAT study results and DMC's decision to stop PARADIGM study ahead of schedule in March 2014 based on the positive efficacy findings are included in the background of the study in Introduction.
06 May 2015	Modified several study objectives and endpoints (secondary and exploratory endpoints) and their associated analysis plans, included cognitive function assessments using the Mini-Mental State Examination (MMSE) instrument at baseline and annually thereafter, modified several entry criteria, moved the interim efficacy analysis to occur when approximately two-thirds of the primary composite events, rather than half as previously defined and eliminated the futility analysis.
04 December 2015	Administered KCCQ at the start of the run-in (i.e., Visit 101 or 102), whichever occurs first. Included a process for conducting a medical review of medical history of enrolled patients by a Novartis central review group to assess adherence to the inclusion/exclusion criteria. Adjust sample size from 4300 to 4600 to increase the statistical power from 81% to 85% to detect a 25% reduction in recurrent heart failure hospitalizations.
09 December 2015	The purpose of this amendment was to include changes required by the Japanese Health Authority (PMDA) and the Indian Health Authority. Changes made were only applicable to Japan and India.

Notes:

---

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported