

**Clinical trial results:****Study to Evaluate the Effect of Dapagliflozin on the Incidence of Worsening Heart Failure or Cardiovascular Death in Patients With Chronic Heart Failure (DAPA-HF)****Summary**

EudraCT number	2016-003897-41
Trial protocol	SE CZ DE DK BG SK PL
Global end of trial date	17 July 2019

Results information

Result version number	v1 (current)
This version publication date	22 July 2020
First version publication date	22 July 2020

Trial information**Trial identification**

Sponsor protocol code	D1699C00001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03036124
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca AB
Sponsor organisation address	151 85, Södertälje, Sweden,
Public contact	AstraZeneca Information Centre, AstraZeneca, +1 8772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 July 2019
Is this the analysis of the primary	Yes

completion data?	
Primary completion date	17 July 2019
Global end of trial reached?	Yes
Global end of trial date	17 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether dapagliflozin is superior to placebo, when added to standard of care, in reducing the incidence of CV death or a HF event (hospitalisation for HF or equivalent HF event, i.e., an urgent HF visit).

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 February 2017
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	China: 237
Country: Number of subjects enrolled	India: 237
Country: Number of subjects enrolled	Japan: 343
Country: Number of subjects enrolled	Taiwan: 141
Country: Number of subjects enrolled	Vietnam: 138
Country: Number of subjects enrolled	Bulgaria: 266
Country: Number of subjects enrolled	Czech Republic: 210
Country: Number of subjects enrolled	Denmark: 99
Country: Number of subjects enrolled	Germany: 186
Country: Number of subjects enrolled	Hungary: 250
Country: Number of subjects enrolled	Netherlands: 135
Country: Number of subjects enrolled	Poland: 290
Country: Number of subjects enrolled	Russian Federation: 422
Country: Number of subjects enrolled	Slovakia: 166
Country: Number of subjects enrolled	Sweden: 68
Country: Number of subjects enrolled	United Kingdom: 62
Country: Number of subjects enrolled	Canada: 223
Country: Number of subjects enrolled	United States: 454
Country: Number of subjects enrolled	Argentina: 297
Country: Number of subjects enrolled	Brazil: 520
Worldwide total number of subjects	4744
EEA total number of subjects	1732

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)	1878
From 65 to 84 years	2745
85 years and over	121

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

In DAPA-HFat the first visit, i.e. the enrollment visit 1, patients were evaluated regarding the protocol mandated inclusion and exclusion criteria.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dapa 10mg

Arm description:

Dapagliflozin 10 mg tablets administered orally once daily

Arm type	Active comparator
Investigational medicinal product name	Dapagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dapagliflozin 10 mg tablets administered orally once daily

Arm title	Placebo
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Arm description:

Matching placebo for dapagliflozin 10 mg administered orally once daily

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

Dosage and administration details:

Matching placebo for dapagliflozin 10 mg administered orally once daily

Number of subjects in period 1	Dapa 10mg	Placebo
Started	2373	2371
Completed	2368	2365
Not completed	5	6
Consent withdrawn by subject	5	4

Lost to follow-up	-	2
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Baseline characteristics

Reporting groups

Reporting group title	Dapa 10mg
Reporting group description: Dapagliflozin 10 mg tablets administered orally once daily	
Reporting group title	Placebo
Reporting group description: Matching placebo for dapagliflozin 10 mg administered orally once daily	

Reporting group values	Dapa 10mg	Placebo	Total
Number of subjects	2373	2371	4744
Age Categorical Units: Participants			
<=50	208	188	396
>50	2165	2183	4348
Age Continuous Units: Years			
arithmetic mean	66.2	66.5	-
standard deviation	± 11.0	± 10.8	-
Sex: Female, Male Units: Participants			
Female	564	545	1109
Male	1809	1826	3635
Age, Customized Units: Subjects			
<=65	1032	998	2030
66 - 75	825	886	1711
>75	516	487	1003
Race/Ethnicity, Customized Units: Subjects			
White	1662	1671	3333
Black or African American	122	104	226
Asian	552	564	1116
Native Hawaiian or other Pacific Islander	0	2	2
American Indian or Alaska Native	3	1	4
Other	34	29	63
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	381	387	768
Not Hispanic or Latino	1992	1984	3976
Unknown or Not Reported	0	0	0
Main etiology of HF Units: Subjects			
Ischaemic	1316	1358	2674
Non-Ischaemic	857	830	1687
Unknown	200	183	383
Prior HF hospitalization			

Units: Subjects			
Yes	1124	1127	2251
No	1249	1244	2493
NYHA class at enrolment			
Units: Subjects			
II	1606	1597	3203
III	747	751	1498
IV	20	23	43
Type 2 diabetes at baseline			
Units: Subjects			
Yes	1075	1064	2139
No	1298	1307	2605
LVEF			
Units: Percent			
arithmetic mean	31.2	30.9	
standard deviation	± 6.7	± 6.9	-

Subject analysis sets

Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description:	
All randomized subjects.	

Reporting group values	Full Analysis Set		
Number of subjects	4744		
Age Categorical			
Units: Participants			
<=50	396		
>50	4348		
Age Continuous			
Units: Years			
arithmetic mean	66.3		
standard deviation	± 10.9		
Sex: Female, Male			
Units: Participants			
Female			
Male			
Age, Customized			
Units: Subjects			
<=65			
66 - 75			
>75			
Race/Ethnicity, Customized			
Units: Subjects			
White			
Black or African American			
Asian			
Native Hawaiian or other Pacific Islander			
American Indian or Alaska Native			

Other			
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown or Not Reported			
Main etiology of HF			
Units: Subjects			
Ischaemic			
Non-Ischaemic			
Unknown			
Prior HF hospitalization			
Units: Subjects			
Yes			
No			
NYHA class at enrolment			
Units: Subjects			
II			
III			
IV			
Type 2 diabetes at baseline			
Units: Subjects			
Yes			
No			
LVEF			
Units: Percent			
arithmetic mean	31.1		
standard deviation	± 6.8		

End points

End points reporting groups

Reporting group title	Dapa 10mg
Reporting group description:	
Dapagliflozin 10 mg tablets administered orally once daily	
Reporting group title	Placebo
Reporting group description:	
Matching placebo for dapagliflozin 10 mg administered orally once daily	
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description:	
All randomized subjects.	

Primary: Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure.

End point title	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure.
End point description:	
Primary efficacy	
End point type	Primary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: Participants	386	502	386	

Statistical analyses

Statistical analysis title	Cox regression
Comparison groups	Dapa 10mg v Placebo v Full Analysis Set
Number of subjects included in analysis	7117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65

upper limit	0.85
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Secondary: Subjects Included in the Composite Endpoint of CV Death or Hospitalization Due to Heart Failure.

End point title	Subjects Included in the Composite Endpoint of CV Death or Hospitalization Due to Heart Failure.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: Participants	382	495	382	

Statistical analyses

Statistical analysis title	Cox regression
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.85

Secondary: Events Included in the Composite Endpoint of Recurrent Hospitalizations Due to Heart Failure and CV Death.

End point title	Events Included in the Composite Endpoint of Recurrent Hospitalizations Due to Heart Failure and CV Death.
End point description:	
Secondary	
End point type	Secondary

End point timeframe:

Up to 27.8 months.

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: HF events or CVD.	567	742	567	

Statistical analyses

Statistical analysis title	Recurrent event analysis
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	LWYY proportional rates model
Parameter estimate	Rate Ratio (RR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.88

Secondary: Change from baseline in the KCCQ total symptom score

End point title	Change from baseline in the KCCQ total symptom score
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: 1-point in the scale of 0 to 100.	2252	2235	2252	

Statistical analyses

Statistical analysis title	Win ratio analysis
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 ^[1]
Method	Win Ratio
Parameter estimate	Win Ratio (WR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.26

Notes:

[1] - The p-value is obtained from a rank ANCOVA adjusted for baseline KCCQ score and stratified by T2DM status at randomization.

Secondary: Subjects Included in the Composite Endpoint of $\geq 50\%$ sustained decline in eGFR, ESRD or Renal death.

End point title	Subjects Included in the Composite Endpoint of $\geq 50\%$ sustained decline in eGFR, ESRD or Renal death.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2371	2371	2373	
Units: Participants	28	39	28	

Statistical analyses

Statistical analysis title	Cox regression
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744

Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1681
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	1.16

Secondary: Subjects Included in the Endpoint of All-cause Mortality.

End point title	Subjects Included in the Endpoint of All-cause Mortality.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: Participants	276	329	276	

Statistical analyses

Statistical analysis title	Cox regression
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0217
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.97

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug until last study visit

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22.0
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Reporting groups

Reporting group title	Dapa 10mg
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Dapa 10mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	895 / 2368 (37.80%)	994 / 2368 (41.98%)	
number of deaths (all causes)	287	335	
number of deaths resulting from adverse events	286	333	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiodysplasia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	

Aortic dissection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic vascular disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dry gangrene			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extremity necrosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematocoele			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	7 / 2368 (0.30%)	11 / 2368 (0.46%)	
occurrences causally related to treatment / all	1 / 9	4 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery occlusion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	11 / 2368 (0.46%)	10 / 2368 (0.42%)	
occurrences causally related to treatment / all	0 / 11	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral embolism			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	9 / 2368 (0.38%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 11	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Shock			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	

Adenocarcinoma of colon			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Basal cell carcinoma			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign breast neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign uterine neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neoplasm			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	

occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Breast cancer female			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer recurrent			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brenner tumour			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangiocarcinoma			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chronic lymphocytic leukaemia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	

deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer metastatic subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric cancer subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal cancer metastatic subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	

Glioblastoma multiforme	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 1	0 / 0
Hepatocellular carcinoma	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine benign neoplasm	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 1	0 / 0
Leukaemia	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
	occurrences causally related to treatment / all	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 1
Leukaemia recurrent	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma	subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
	occurrences causally related to treatment / all	0 / 1	0 / 2
	deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic	subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 3	0 / 0
	deaths causally related to treatment / all	0 / 2	0 / 0
Lung neoplasm malignant	subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)

occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 3	
Malignant melanoma			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Meningioma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic carcinoma of the bladder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelofibrosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal cavity cancer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cancer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatic neoplasm			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Papillary renal cell carcinoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary tumour benign			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleomorphic adenoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	6 / 2368 (0.25%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	1 / 1	

Squamous cell carcinoma			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tonsil cancer			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Immune system disorders			
Heart transplant rejection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	

deaths causally related to treatment / all	0 / 0	0 / 2	
Chest discomfort			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	4 / 2368 (0.17%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Complication associated with device			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	48 / 2368 (2.03%)	48 / 2368 (2.03%)	
occurrences causally related to treatment / all	0 / 48	1 / 48	
deaths causally related to treatment / all	0 / 48	1 / 48	
General physical health deterioration			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site inflammation			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Necrosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	6 / 2368 (0.25%)	16 / 2368 (0.68%)	
occurrences causally related to treatment / all	0 / 6	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sudden cardiac death			
subjects affected / exposed	18 / 2368 (0.76%)	27 / 2368 (1.14%)	
occurrences causally related to treatment / all	0 / 18	0 / 27	
deaths causally related to treatment / all	0 / 18	0 / 27	
Sudden death			
subjects affected / exposed	19 / 2368 (0.80%)	10 / 2368 (0.42%)	
occurrences causally related to treatment / all	2 / 19	0 / 10	
deaths causally related to treatment / all	2 / 19	0 / 10	
Ulcer haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent occlusion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Confusional state			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to	0 / 1	0 / 2	

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar I disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomyosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balanoposthitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis noninfective			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone contusion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain herniation			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve rupture			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Compression fracture			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	1 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	

deaths causally related to treatment / all	0 / 0	0 / 0	
Fibula fracture			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	7 / 2368 (0.30%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	1 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint dislocation			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Lumbar vertebral fracture			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Poisoning			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	

occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Skin injury subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fractured base subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic injury			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	4 / 2368 (0.17%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	1 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tendon injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Traumatic intracranial haemorrhage subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatinine increased subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular filtration rate decreased subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio			

increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial pressure increased			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	5 / 2368 (0.21%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Acute myocardial infarction			
subjects affected / exposed	37 / 2368 (1.56%)	38 / 2368 (1.60%)	
occurrences causally related to treatment / all	1 / 37	1 / 40	
deaths causally related to treatment / all	1 / 11	0 / 9	
Angina pectoris			
subjects affected / exposed	12 / 2368 (0.51%)	12 / 2368 (0.51%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	

Angina unstable			
subjects affected / exposed	21 / 2368 (0.89%)	30 / 2368 (1.27%)	
occurrences causally related to treatment / all	0 / 24	0 / 31	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	2 / 2368 (0.08%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 2	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 5	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	26 / 2368 (1.10%)	39 / 2368 (1.65%)	
occurrences causally related to treatment / all	0 / 27	0 / 43	
deaths causally related to treatment / all	0 / 0	0 / 2	
Atrial flutter			
subjects affected / exposed	8 / 2368 (0.34%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial thrombosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradyarrhythmia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	2 / 2368 (0.08%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bundle branch block left			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac aneurysm			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	9 / 2368 (0.38%)	10 / 2368 (0.42%)	
occurrences causally related to treatment / all	0 / 9	0 / 10	
deaths causally related to treatment / all	0 / 6	0 / 7	
Cardiac disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	262 / 2368 (11.06%)	351 / 2368 (14.82%)	
occurrences causally related to treatment / all	8 / 380	8 / 523	
deaths causally related to treatment / all	0 / 53	1 / 76	
Cardiac failure acute			
subjects affected / exposed	42 / 2368 (1.77%)	59 / 2368 (2.49%)	
occurrences causally related to treatment / all	1 / 58	3 / 75	
deaths causally related to treatment / all	0 / 11	0 / 13	
Cardiac failure chronic			
subjects affected / exposed	27 / 2368 (1.14%)	33 / 2368 (1.39%)	
occurrences causally related to treatment / all	0 / 32	0 / 46	
deaths causally related to treatment / all	0 / 8	0 / 9	
Cardiac failure congestive			
subjects affected / exposed	65 / 2368 (2.74%)	70 / 2368 (2.96%)	
occurrences causally related to treatment / all	2 / 102	4 / 106	
deaths causally related to treatment / all	1 / 9	0 / 13	
Cardiac tamponade			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiogenic shock			
subjects affected / exposed	9 / 2368 (0.38%)	15 / 2368 (0.63%)	
occurrences causally related to treatment / all	0 / 10	0 / 16	
deaths causally related to treatment / all	0 / 6	0 / 11	

Cardiomyopathy			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Cardiorenal syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiovascular insufficiency			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic left ventricular failure			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congestive cardiomyopathy			
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery disease			
subjects affected / exposed	9 / 2368 (0.38%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 1	
Coronary artery insufficiency			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Coronary artery stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	

occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrasystoles			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Frederick's syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cardiomyopathy			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Low cardiac output syndrome			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial fibrosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial infarction			
subjects affected / exposed	16 / 2368 (0.68%)	17 / 2368 (0.72%)	
occurrences causally related to treatment / all	1 / 16	0 / 17	
deaths causally related to treatment / all	0 / 7	0 / 7	
Myocardial ischaemia			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Palpitations			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prosthetic cardiac valve thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Right ventricular failure			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	

Sinus node dysfunction			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	6 / 2368 (0.25%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Ventricular extrasystoles			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	11 / 2368 (0.46%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 2	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	34 / 2368 (1.44%)	54 / 2368 (2.28%)	
occurrences causally related to treatment / all	1 / 41	1 / 65	
deaths causally related to treatment / all	0 / 1	0 / 2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 2368 (0.13%)	11 / 2368 (0.46%)	
occurrences causally related to treatment / all	0 / 4	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coagulopathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to	1 / 2	0 / 0	

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukopenia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	7 / 2368 (0.30%)	14 / 2368 (0.59%)	
occurrences causally related to treatment / all	0 / 9	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 3	
Aspiration			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	14 / 2368 (0.59%)	22 / 2368 (0.93%)	

occurrences causally related to treatment / all	0 / 16	0 / 34	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic respiratory failure			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	4 / 2368 (0.17%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eosinophilic pneumonia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cyst			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal lesion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleurisy			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumomediastinum			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia aspiration			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pneumonitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumothorax spontaneous subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism subjects affected / exposed	7 / 2368 (0.30%)	14 / 2368 (0.59%)	
occurrences causally related to treatment / all	0 / 7	1 / 14	
deaths causally related to treatment / all	0 / 3	1 / 6	
Pulmonary hypertension subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary toxicity subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary vasculitis subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	3 / 2368 (0.13%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 4	
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain stem infarction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebellar stroke			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to	0 / 0	0 / 2	

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	8 / 2368 (0.34%)	11 / 2368 (0.46%)	
occurrences causally related to treatment / all	2 / 9	1 / 12	
deaths causally related to treatment / all	0 / 3	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cerebral thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	7 / 2368 (0.30%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 3	
Diabetic ketoacidotic hyperglycaemic coma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Dizziness			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Haemorrhagic stroke			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Haemorrhagic transformation stroke			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Headache			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	24 / 2368 (1.01%)	26 / 2368 (1.10%)	
occurrences causally related to treatment / all	0 / 26	0 / 28	
deaths causally related to treatment / all	0 / 4	0 / 6	

Loss of consciousness			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peroneal nerve palsy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	7 / 2368 (0.30%)	13 / 2368 (0.55%)	
occurrences causally related to treatment / all	1 / 7	4 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	13 / 2368 (0.55%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 13	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular dementia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular encephalopathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery occlusion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paresis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Angle closure glaucoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strabismus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	

deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic gastritis			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	4 / 2368 (0.17%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Duodenal ulcer perforation			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis haemorrhagic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiectasia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	4 / 2368 (0.17%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 5	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastrointestinal polyp haemorrhage			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal ulcer			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	9 / 2368 (0.38%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intestinal ischaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Megacolon			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pancreatitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 6	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis mesenteric vessel subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Umbilical hernia subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct obstruction subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cholecystitis acute			
subjects affected / exposed	6 / 2368 (0.25%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cholecystitis chronic			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cryptogenic cirrhosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder enlargement			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	23 / 2368 (0.97%)	46 / 2368 (1.94%)	
occurrences causally related to treatment / all	2 / 25	5 / 49	
deaths causally related to treatment / all	0 / 3	0 / 1	
Anuria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 4	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis noninfective			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to	0 / 2	0 / 1	

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy toxic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postrenal failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	8 / 2368 (0.34%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	1 / 8	1 / 9	
deaths causally related to treatment / all	1 / 2	0 / 0	
Renal impairment			
subjects affected / exposed	7 / 2368 (0.30%)	13 / 2368 (0.55%)	
occurrences causally related to treatment / all	1 / 7	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal injury			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Product issues			
Device dislocation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device inappropriate shock delivery			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device lead issue			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lead dislodgement			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Dermatitis allergic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug eruption			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Petechiae			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriasis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin necrosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	

occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint effusion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle spasms			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	5 / 2368 (0.21%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteonecrosis of jaw			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural mass			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polymyalgia rheumatica			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudarthrosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal pain			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Spinal stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondyloarthropathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	10 / 2368 (0.42%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	

Diabetes mellitus		
subjects affected / exposed	5 / 2368 (0.21%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	6 / 2368 (0.25%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)

occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	1 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steroid diabetes			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Biliary sepsis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	12 / 2368 (0.51%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 13	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cellulitis			
subjects affected / exposed	9 / 2368 (0.38%)	10 / 2368 (0.42%)	
occurrences causally related to treatment / all	0 / 11	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis gangrenous			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridial infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	

occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated tuberculosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Diverticulitis			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Endocarditis bacterial			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Endotoxic shock			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fournier's gangrene			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene			
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 5	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster oticus			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infectious pleural effusion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal sepsis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	4 / 2368 (0.17%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 7	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lyme disease			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mediastinal abscess			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis tuberculous			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	7 / 2368 (0.30%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	1 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Otitis media acute			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perichondritis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periodontitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Peritonsillar abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	76 / 2368 (3.21%)	82 / 2368 (3.46%)	
occurrences causally related to treatment / all	0 / 83	1 / 87	
deaths causally related to treatment / all	0 / 9	0 / 8	
Pneumonia bacterial			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelocystitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rickettsiosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	13 / 2368 (0.55%)	14 / 2368 (0.59%)	
occurrences causally related to treatment / all	1 / 13	0 / 14	
deaths causally related to treatment / all	1 / 5	0 / 6	
Septic shock			
subjects affected / exposed	8 / 2368 (0.34%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 9	0 / 9	
deaths causally related to treatment / all	0 / 4	0 / 1	
Sinusitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Subdiaphragmatic abscess			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic candida			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	11 / 2368 (0.46%)	17 / 2368 (0.72%)	
occurrences causally related to treatment / all	7 / 13	4 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	4 / 2368 (0.17%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 4	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	5 / 2368 (0.21%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Dapa 10mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	928 / 2368 (39.19%)	955 / 2368 (40.33%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	88 / 2368 (3.72%)	73 / 2368 (3.08%)	
occurrences (all)	98	81	
Accelerated hypertension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Aortic aneurysm			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Aortic dilatation			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Aortic stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Aortic thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Arterial stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Circulatory collapse			

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Deep vein thrombosis		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Dry gangrene		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Flushing		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Haematoma		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	1	4
Hypertension		
subjects affected / exposed	17 / 2368 (0.72%)	19 / 2368 (0.80%)
occurrences (all)	19	21
Hypertensive crisis		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Hypertensive urgency		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hypovolaemic shock		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Intermittent claudication		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Lymphatic fistula		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Orthostatic hypotension		
subjects affected / exposed	10 / 2368 (0.42%)	5 / 2368 (0.21%)
occurrences (all)	10	5
Peripheral arterial occlusive disease		

subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)
occurrences (all)	7	3
Peripheral artery occlusion		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Peripheral artery stenosis		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Peripheral coldness		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Peripheral embolism		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Peripheral ischaemia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Peripheral venous disease		
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)
occurrences (all)	3	0
Phlebitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Poor peripheral circulation		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Raynaud's phenomenon		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Subclavian artery stenosis		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Subclavian vein thrombosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Thrombophlebitis superficial		

subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Varicose ulceration			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Varicose vein			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
Vasculitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Venous thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Anogenital warts			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Basal cell carcinoma			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Benign lung neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Benign neoplasm of adrenal gland			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Bladder cancer			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

Bowen's disease		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Colon adenoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Colon cancer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cutaneous T-cell lymphoma recurrent		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	2
Eyelid tumour		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Lipoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Lung neoplasm		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Plasma cell myeloma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Prostate cancer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Renal cancer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Seborrhoeic keratosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Squamous cell carcinoma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences (all)	1	0	
Squamous cell carcinoma of skin subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Thyroid adenoma subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Uterine leiomyoma subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Contrast media allergy subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Drug hypersensitivity subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Hypersensitivity subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Seasonal allergy subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Administration site phlebitis subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Asthenia subjects affected / exposed	7 / 2368 (0.30%)	4 / 2368 (0.17%)	
occurrences (all)	7	4	
Catheter site pain subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Chest discomfort subjects affected / exposed	5 / 2368 (0.21%)	5 / 2368 (0.21%)	
occurrences (all)	5	5	

Chest pain		
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)
occurrences (all)	4	4
Chills		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Complication associated with device		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Disuse syndrome		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Drug intolerance		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Fatigue		
subjects affected / exposed	15 / 2368 (0.63%)	11 / 2368 (0.46%)
occurrences (all)	15	12
Feeling abnormal		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Gait disturbance		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Hernia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Impaired healing		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Implant site extravasation		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Influenza like illness		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0

Infusion site extravasation		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Malaise		
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)
occurrences (all)	6	4
Medical device site haematoma		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Medical device site pain		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Non-cardiac chest pain		
subjects affected / exposed	5 / 2368 (0.21%)	4 / 2368 (0.17%)
occurrences (all)	5	4
Oedema		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Oedema peripheral		
subjects affected / exposed	13 / 2368 (0.55%)	29 / 2368 (1.22%)
occurrences (all)	14	31
Pain		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Peripheral swelling		
subjects affected / exposed	5 / 2368 (0.21%)	8 / 2368 (0.34%)
occurrences (all)	5	8
Pyrexia		
subjects affected / exposed	1 / 2368 (0.04%)	11 / 2368 (0.46%)
occurrences (all)	1	12
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Thirst		
subjects affected / exposed	5 / 2368 (0.21%)	0 / 2368 (0.00%)

occurrences (all)	5	0	
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Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Affective disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences (all)	4	6	
Confusional state			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Delirium			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences (all)	3	7	
Depressed mood			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	5 / 2368 (0.21%)	6 / 2368 (0.25%)	
occurrences (all)	5	6	
Disorientation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Emotional disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

Insomnia			
subjects affected / exposed	9 / 2368 (0.38%)	12 / 2368 (0.51%)	
occurrences (all)	10	12	
Intensive care unit delirium			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Mental status changes			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	2	
Organic brain syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Panic reaction			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Sleep disorder			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Acquired phimosis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Balanoposthitis			
subjects affected / exposed	8 / 2368 (0.34%)	1 / 2368 (0.04%)	
occurrences (all)	10	1	
Benign prostatic hyperplasia			
subjects affected / exposed	7 / 2368 (0.30%)	9 / 2368 (0.38%)	
occurrences (all)	7	9	
Erectile dysfunction			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Genital haemorrhage			

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Gynaecomastia			
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)	
occurrences (all)	4	8	
Pelvic pain			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Penile oedema			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Pruritus genital			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Scrotal haematocoele			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Vulvar erosion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Ankle fracture			
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)	
occurrences (all)	5	2	
Arthropod bite			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Arthropod sting			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

Bone contusion		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Bone fissure		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Chest injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Chillblains		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Clavicle fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Compression fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Contusion		
subjects affected / exposed	10 / 2368 (0.42%)	9 / 2368 (0.38%)
occurrences (all)	10	10
Craniocerebral injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Face injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Facial bones fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Fall		
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)
occurrences (all)	5	3
Fibula fracture		
subjects affected / exposed	0 / 2368 (0.00%)	4 / 2368 (0.17%)
occurrences (all)	0	4

Foot fracture		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Forearm fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Frostbite		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hand fracture		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Head injury		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Heat illness		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Joint dislocation		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Joint injury		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Ligament injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Ligament sprain		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	4	2

Limb injury		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Lower limb fracture		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Lumbar vertebral fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Meniscus injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Mouth injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Muscle rupture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Muscle strain		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Osteochondral fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Patella fracture		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Post procedural haematoma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Post procedural haemorrhage		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Post-traumatic neck syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0

Postoperative delirium		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Procedural pain		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Pseudophakic bullous keratopathy		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Radius fracture		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Reactive gastropathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Rib fracture		
subjects affected / exposed	2 / 2368 (0.08%)	8 / 2368 (0.34%)
occurrences (all)	2	8
Road traffic accident		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Scratch		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Skin abrasion		
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)
occurrences (all)	4	3
Skin injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Skin laceration		
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)
occurrences (all)	6	2
Skull fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0

Spinal column injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Spinal compression fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Spinal cord injury cervical		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Subcutaneous haematoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Tendon injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Tooth fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Tooth injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Toxicity to various agents		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Upper limb fracture		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Wound		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	1	5
Wound complication		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1

Wound haemorrhage subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Wrist fracture subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	1 / 2368 (0.04%) 1	
Investigations			
Bleeding time prolonged subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Acinetobacter test positive subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Blood creatine increased subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Blood creatinine increased subjects affected / exposed occurrences (all)	24 / 2368 (1.01%) 27	25 / 2368 (1.06%) 26	
Blood glucose increased subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Blood potassium decreased subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 3	1 / 2368 (0.04%) 1	
Blood potassium increased subjects affected / exposed occurrences (all)	11 / 2368 (0.46%) 12	1 / 2368 (0.04%) 1	
Blood pressure decreased subjects affected / exposed occurrences (all)	4 / 2368 (0.17%) 4	1 / 2368 (0.04%) 1	
Blood pressure increased			

subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Blood thyroid stimulating hormone increased		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Blood urea increased		
subjects affected / exposed	9 / 2368 (0.38%)	5 / 2368 (0.21%)
occurrences (all)	9	5
Blood uric acid increased		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Brain natriuretic peptide increased		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
C-reactive protein increased		
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)
occurrences (all)	3	5
Candida test positive		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cardiac murmur		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cardioactive drug level increased		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cardiovascular evaluation		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Coagulation time shortened		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Ejection fraction decreased		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0

Eosinophil count increased		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Gamma-glutamyltransferase increased		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Glomerular filtration rate abnormal		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Glomerular filtration rate decreased		
subjects affected / exposed	15 / 2368 (0.63%)	21 / 2368 (0.89%)
occurrences (all)	16	22
Glycosylated haemoglobin increased		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	3	2
Haematocrit increased		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Haemoglobin decreased		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Heart rate increased		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Helicobacter test positive		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Hepatic enzyme increased		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
International normalised ratio increased		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	1	4
Intraocular pressure increased		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences (all)	1	0
Liver function test abnormal subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Liver function test increased subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Low density lipoprotein increased subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
N-terminal prohormone brain natriuretic peptide increased subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences (all)	2	4
Occult blood positive subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Oxygen saturation decreased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Platelet count decreased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Renal function test abnormal subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Transaminases increased subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Urine analysis abnormal subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Vitamin B12 decreased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Weight decreased		

subjects affected / exposed occurrences (all)	4 / 2368 (0.17%) 4	6 / 2368 (0.25%) 6	
Weight increased subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	10 / 2368 (0.42%) 10	
Cardiac disorders			
Atrial fibrillation subjects affected / exposed occurrences (all)	58 / 2368 (2.45%) 63	52 / 2368 (2.20%) 55	
Cardiac failure subjects affected / exposed occurrences (all)	76 / 2368 (3.21%) 90	130 / 2368 (5.49%) 154	
Acute coronary syndrome subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Angina pectoris subjects affected / exposed occurrences (all)	8 / 2368 (0.34%) 10	17 / 2368 (0.72%) 22	
Acute myocardial infarction subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Angina unstable subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	2 / 2368 (0.08%) 2	
Arrhythmia subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	2 / 2368 (0.08%) 2	
Arteriosclerosis coronary artery subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Atrial flutter subjects affected / exposed occurrences (all)	10 / 2368 (0.42%) 10	9 / 2368 (0.38%) 9	
Atrial tachycardia subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 6	6 / 2368 (0.25%) 6	

Atrial thrombosis		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Atrioventricular block		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Atrioventricular block complete		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Atrioventricular block first degree		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Bradyarrhythmia		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Bradycardia		
subjects affected / exposed	3 / 2368 (0.13%)	7 / 2368 (0.30%)
occurrences (all)	3	7
Bundle branch block left		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Cardiac aneurysm		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Bundle branch block right		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cardiac asthma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cardiac failure acute		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences (all)	2	5
Cardiac failure chronic		
subjects affected / exposed	4 / 2368 (0.17%)	10 / 2368 (0.42%)
occurrences (all)	5	12

Cardiac failure congestive subjects affected / exposed occurrences (all)	15 / 2368 (0.63%) 16	12 / 2368 (0.51%) 14
Cardiac ventricular thrombosis subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0
Cardiomegaly subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1
Cardiomyopathy subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0
Chronotropic incompetence subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1
Coronary artery disease subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	5 / 2368 (0.21%) 5
Coronary artery stenosis subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	2 / 2368 (0.08%) 2
Extrasystoles subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	1 / 2368 (0.04%) 1
Intracardiac thrombus subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	2 / 2368 (0.08%) 2
Left ventricular dysfunction subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0
Left ventricular failure subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	0 / 2368 (0.00%) 0
Left ventricular hypertrophy subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0

Mitral valve disease		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Mitral valve incompetence		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Myocardial infarction		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Myocardial ischaemia		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Palpitations		
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)
occurrences (all)	4	10
Pericardial effusion		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Pericardial haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Sinus arrest		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Sinus bradycardia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Sinus node dysfunction		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Sinus tachycardia		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Tachycardia		
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)
occurrences (all)	3	3

Tachycardia paroxysmal subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Tricuspid valve incompetence subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	2 / 2368 (0.08%) 2	
Ventricular arrhythmia subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	1 / 2368 (0.04%) 1	
Ventricular extrasystoles subjects affected / exposed occurrences (all)	3 / 2368 (0.13%) 3	4 / 2368 (0.17%) 4	
Ventricular fibrillation subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	2 / 2368 (0.08%) 2	
Ventricular tachyarrhythmia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ventricular tachycardia subjects affected / exposed occurrences (all)	12 / 2368 (0.51%) 19	18 / 2368 (0.76%) 22	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Anaemia subjects affected / exposed occurrences (all)	10 / 2368 (0.42%) 10	13 / 2368 (0.55%) 13	
Blood loss anaemia subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	1 / 2368 (0.04%) 1	
Hypochromic anaemia subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Iron deficiency anaemia subjects affected / exposed	4 / 2368 (0.17%)	10 / 2368 (0.42%)	

occurrences (all)	4	10	
Leukocytosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Lymphadenopathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Microcytic anaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Nephrogenic anaemia			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	
occurrences (all)	3	3	
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Normocytic anaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Polycythaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Splenomegaly			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Thrombocytopenia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

Asthma		
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)
occurrences (all)	4	3
Bronchial disorder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Bronchitis chronic		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Chronic obstructive pulmonary disease		
subjects affected / exposed	6 / 2368 (0.25%)	10 / 2368 (0.42%)
occurrences (all)	7	12
Cough		
subjects affected / exposed	14 / 2368 (0.59%)	18 / 2368 (0.76%)
occurrences (all)	16	19
Dysphonia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dyspnoea		
subjects affected / exposed	20 / 2368 (0.84%)	33 / 2368 (1.39%)
occurrences (all)	22	35
Dyspnoea exertional		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Dyspnoea paroxysmal nocturnal		
subjects affected / exposed	0 / 2368 (0.00%)	4 / 2368 (0.17%)
occurrences (all)	0	4
Emphysema		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Epistaxis		
subjects affected / exposed	8 / 2368 (0.34%)	8 / 2368 (0.34%)
occurrences (all)	9	8
Haemoptysis		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	1	4

Hiccups		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Nasal congestion		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Nasal polyps		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Obstructive airways disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Oropharyngeal pain		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Pleural effusion		
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)
occurrences (all)	2	6
Pleural fibrosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Pleural thickening		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Pleurisy		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Pneumonia aspiration		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Pneumothorax		
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)
occurrences (all)	3	0
Productive cough		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3

Pulmonary calcification		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Pulmonary congestion		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	1	4
Pulmonary embolism		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Pulmonary hypertension		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Pulmonary mass		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Pulmonary oedema		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Respiratory disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Respiratory failure		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Rhinitis allergic		
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)
occurrences (all)	3	1
Rhinorrhoea		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Sleep apnoea syndrome		
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)
occurrences (all)	3	3
Tachypnoea		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2

Throat irritation subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Upper respiratory tract inflammation subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	6 / 2368 (0.25%) 7	
Wheezing subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Nervous system disorders			
Ageusia subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Aphasia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ataxia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Autonomic neuropathy subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Balance disorder subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Brain oedema subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Carotid arteriosclerosis subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Carotid artery disease subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Carotid artery occlusion subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0
Carotid artery stenosis		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Cerebral atrophy		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Cerebrovascular accident		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cerebrovascular disorder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cognitive disorder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dementia		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	3	2
Dementia Alzheimer's type		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Diplegia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Diabetic neuropathy		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Disturbance in attention		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dizziness		
subjects affected / exposed	44 / 2368 (1.86%)	26 / 2368 (1.10%)

occurrences (all)	49	28
Dizziness postural		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Dysdiadochokinesis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dysgeusia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Facial paralysis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Headache		
subjects affected / exposed	10 / 2368 (0.42%)	8 / 2368 (0.34%)
occurrences (all)	10	8
Hypoaesthesia		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Hypotonia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Ischaemic stroke		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Lacunar infarction		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Leukoencephalopathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Loss of consciousness		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Memory impairment		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)

occurrences (all)	1	1
Migraine		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Myoclonus		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Neuropathy peripheral		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Nystagmus		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Paraesthesia		
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)
occurrences (all)	4	1
Peripheral nerve paresis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Peroneal nerve palsy		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Polyneuropathy		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Post herpetic neuralgia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Presyncope		
subjects affected / exposed	5 / 2368 (0.21%)	1 / 2368 (0.04%)
occurrences (all)	6	1
Psychomotor hyperactivity		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Radiculopathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences (all)	1	0	
Reduced facial expression			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Retrograde amnesia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Sciatica			
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences (all)	2	6	
Somnolence			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Syncope			
subjects affected / exposed	6 / 2368 (0.25%)	9 / 2368 (0.38%)	
occurrences (all)	6	10	
Taste disorder			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Transient ischaemic attack			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Tremor			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Uraemic encephalopathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Visual field defect			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Blepharitis			

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cataract		
subjects affected / exposed	6 / 2368 (0.25%)	14 / 2368 (0.59%)
occurrences (all)	7	15
Conjunctival haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	3
Conjunctivitis allergic		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cornea verticillata		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Dacryostenosis acquired		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Diabetic retinopathy		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Dry eye		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Eye haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Eye irritation		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Eyelid bleeding		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Glaucoma		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Hypermetropia		

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Macular fibrosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Ocular hyperaemia		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Retinal artery occlusion		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Photopsia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Retinal detachment		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Retinal vein occlusion		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Retinal vascular thrombosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Retinopathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Ulcerative keratitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Scintillating scotoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Vision blurred		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Vitreous adhesions		

subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Visual impairment subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Vitreous degeneration subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ear and labyrinth disorders			
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Deafness neurosensory subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Ear canal stenosis subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ear discomfort subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ear haemorrhage subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Eustachian tube dysfunction subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	0 / 2368 (0.00%) 0	
Hypoacusis subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Tinnitus subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	1 / 2368 (0.04%) 1	
Tympanic membrane perforation subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	

Vertigo			
subjects affected / exposed	3 / 2368 (0.13%)	7 / 2368 (0.30%)	
occurrences (all)	3	7	
Vertigo positional			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)	
occurrences (all)	7	3	
Abdominal distension			
subjects affected / exposed	1 / 2368 (0.04%)	5 / 2368 (0.21%)	
occurrences (all)	1	5	
Abdominal hernia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	6 / 2368 (0.25%)	9 / 2368 (0.38%)	
occurrences (all)	6	9	
Abdominal pain lower			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Abdominal pain upper			
subjects affected / exposed	7 / 2368 (0.30%)	4 / 2368 (0.17%)	
occurrences (all)	7	4	
Anal fistula			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Anal fissure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Anal pruritus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Ascites			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	

occurrences (all)	2	1
Aptyalism		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Chronic gastritis		
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)
occurrences (all)	2	3
Coeliac artery stenosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Colitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Colitis ulcerative		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Constipation		
subjects affected / exposed	8 / 2368 (0.34%)	27 / 2368 (1.14%)
occurrences (all)	8	28
Defaecation urgency		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Dental caries		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	3	2
Diarrhoea		
subjects affected / exposed	25 / 2368 (1.06%)	32 / 2368 (1.35%)
occurrences (all)	27	32
Diverticulum intestinal		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Diverticulum		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Dry mouth		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences (all)	1	0
Duodenal ulcer		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Dysphagia		
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)
occurrences (all)	3	1
Dyspepsia		
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)
occurrences (all)	4	1
Enteritis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Enterocolitis		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Erosive oesophagitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Faeces discoloured		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Faeces hard		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Flatulence		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Food poisoning		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Gastric disorder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Gastric polyps		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

occurrences (all)	0	1
Gastric ulcer		
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)
occurrences (all)	3	1
Gastritis		
subjects affected / exposed	6 / 2368 (0.25%)	5 / 2368 (0.21%)
occurrences (all)	7	5
Gastritis erosive		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Gastrointestinal angiodysplasia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Gastrointestinal disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Gastrointestinal haemorrhage		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Gastrooesophageal reflux disease		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Gingival pain		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Gingival swelling		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Glossitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Haematochezia		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

occurrences (all)	0	1
Haemorrhoids		
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)
occurrences (all)	4	1
Hiatus hernia		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Ileus paralytic		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Inguinal hernia		
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)
occurrences (all)	4	2
Irritable bowel syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Large intestinal stenosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Large intestinal ulcer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Large intestine polyp		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Nausea		
subjects affected / exposed	9 / 2368 (0.38%)	8 / 2368 (0.34%)
occurrences (all)	9	9
Lip swelling		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Oesophagitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Pancreatic disorder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences (all)	1	0
Oral pain		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Pancreatitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Periodontal disease		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Peritoneal haemorrhage		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Portal hypertensive gastropathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Rectal haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Stomatitis		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Toothache		
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)
occurrences (all)	4	4
Umbilical hernia		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Upper gastrointestinal haemorrhage		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Varices oesophageal		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	3	1
Vomiting		
subjects affected / exposed	6 / 2368 (0.25%)	5 / 2368 (0.21%)

occurrences (all)	6	5	
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Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Cholelithiasis			
subjects affected / exposed	5 / 2368 (0.21%)	3 / 2368 (0.13%)	
occurrences (all)	5	3	
Cryptogenic cirrhosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hepatic congestion			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Hepatic cyst			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hepatic failure			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	2	
Hepatic function abnormal			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (all)	2	3	
Hepatic steatosis			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
Hepatitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hepatorenal failure			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

Liver disorder subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	1 / 2368 (0.04%) 2	
Liver injury subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Portal hypertension subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Renal and urinary disorders			
Renal impairment subjects affected / exposed occurrences (all)	63 / 2368 (2.66%) 67	56 / 2368 (2.36%) 60	
Azotaemia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Acute kidney injury subjects affected / exposed occurrences (all)	26 / 2368 (1.10%) 28	26 / 2368 (1.10%) 29	
Calculus urinary subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Cystitis haemorrhagic subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Chronic kidney disease subjects affected / exposed occurrences (all)	15 / 2368 (0.63%) 15	18 / 2368 (0.76%) 23	
Diabetic nephropathy subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	1 / 2368 (0.04%) 1	
Dysuria subjects affected / exposed occurrences (all)	6 / 2368 (0.25%) 6	4 / 2368 (0.17%) 4	
Glycosuria subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0
Haematuria		
subjects affected / exposed	5 / 2368 (0.21%)	10 / 2368 (0.42%)
occurrences (all)	5	11
Hypertonic bladder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Incontinence		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Microalbuminuria		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Micturition disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Micturition urgency		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Nephrolithiasis		
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)
occurrences (all)	4	2
Nephropathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Nephropathy toxic		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Nocturia		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Pollakiuria		
subjects affected / exposed	6 / 2368 (0.25%)	3 / 2368 (0.13%)
occurrences (all)	6	3
Polyuria		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)

occurrences (all)	1	1
Prerenal failure		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Proteinuria		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Renal atrophy		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Renal cyst		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	3	2
Renal disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Renal failure		
subjects affected / exposed	37 / 2368 (1.56%)	32 / 2368 (1.35%)
occurrences (all)	39	37
Renal injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Renal mass		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Tubulointerstitial nephritis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Urethral atrophy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Urethral caruncle		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Urethral obstruction		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

occurrences (all)	0	1	
Urethritis noninfective			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Urinary incontinence			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Urinary retention			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences (all)	3	4	
Urinary tract inflammation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Product issues			
Device battery issue			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Device malfunction			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Alopecia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Asteatosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Blister			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Decubitus ulcer			
subjects affected / exposed	0 / 2368 (0.00%)	4 / 2368 (0.17%)	
occurrences (all)	0	4	

Dermatitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dermatitis allergic		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dermatitis contact		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	3	2
Dermatitis exfoliative generalised		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Diabetic foot		
subjects affected / exposed	6 / 2368 (0.25%)	1 / 2368 (0.04%)
occurrences (all)	6	1
Drug eruption		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dry skin		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Ecchymosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Eczema		
subjects affected / exposed	9 / 2368 (0.38%)	4 / 2368 (0.17%)
occurrences (all)	10	4
Eczema asteatotic		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	3
Erythema		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Erythema multiforme		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1

Haemorrhage subcutaneous subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	3 / 2368 (0.13%) 3
Henoch-Schonlein purpura subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1
Hyperhidrosis subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	0 / 2368 (0.00%) 0
Ingrowing nail subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0
Lichenoid keratosis subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1
Lichen sclerosis subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0
Onychomadesis subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1
Peau d'orange subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0
Petechiae subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1
Photosensitivity reaction subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	1 / 2368 (0.04%) 1
Pruritus subjects affected / exposed occurrences (all)	9 / 2368 (0.38%) 10	9 / 2368 (0.38%) 10
Rash subjects affected / exposed occurrences (all)	14 / 2368 (0.59%) 14	11 / 2368 (0.46%) 12

Pruritus generalised		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Rash generalised		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Rash erythematous		
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)
occurrences (all)	3	0
Rash pruritic		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Sebacous hyperplasia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Seborrhoeic dermatitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Skin erosion		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Skin irritation		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Skin lesion		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Skin mass		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Skin ulcer		
subjects affected / exposed	5 / 2368 (0.21%)	8 / 2368 (0.34%)
occurrences (all)	6	8
Swelling face		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0

Urticaria			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (all)	2	3	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	8 / 2368 (0.34%)	12 / 2368 (0.51%)	
occurrences (all)	8	16	
Arthritis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Arthropathy			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Back pain			
subjects affected / exposed	19 / 2368 (0.80%)	27 / 2368 (1.14%)	
occurrences (all)	19	29	
Bone pain			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Bursitis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Costochondritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Dupuytren's contracture			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Exostosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Flank pain			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0
Foot deformity		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Gouty arthritis		
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)
occurrences (all)	3	4
Groin pain		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Intervertebral disc protrusion		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Joint swelling		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Lumbar spinal stenosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Muscle spasms		
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)
occurrences (all)	6	4
Muscle tightness		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Muscular weakness		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Musculoskeletal chest pain		
subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)
occurrences (all)	8	5
Musculoskeletal pain		
subjects affected / exposed	6 / 2368 (0.25%)	3 / 2368 (0.13%)
occurrences (all)	6	3
Musculoskeletal stiffness		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)

occurrences (all)	1	1
Myalgia		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences (all)	2	4
Neck pain		
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)
occurrences (all)	5	3
Osteitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Osteoarthritis		
subjects affected / exposed	10 / 2368 (0.42%)	2 / 2368 (0.08%)
occurrences (all)	10	2
Osteochondrosis		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Osteopenia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Osteoporosis		
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)
occurrences (all)	3	0
Osteosclerosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Pain in extremity		
subjects affected / exposed	12 / 2368 (0.51%)	15 / 2368 (0.63%)
occurrences (all)	12	16
Pain in jaw		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Periarthritis		
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)
occurrences (all)	2	3
Periostitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences (all)	1	0	
Pseudarthrosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Rheumatoid arthritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Rotator cuff syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Scleroderma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Scoliosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Spinal deformity			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Spinal osteoarthritis			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Spinal pain			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Spinal stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Trigger finger			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Vertebral osteophyte			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Endocrine disorders			

Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Diabetes insipidus subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Hyperparathyroidism subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Hyperthyroidism subjects affected / exposed occurrences (all)	5 / 2368 (0.21%) 5	5 / 2368 (0.21%) 5	
Hypoparathyroidism subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Hypothyroidism subjects affected / exposed occurrences (all)	9 / 2368 (0.38%) 9	7 / 2368 (0.30%) 7	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	5 / 2368 (0.21%) 6	7 / 2368 (0.30%) 7	
Dehydration subjects affected / exposed occurrences (all)	25 / 2368 (1.06%) 25	21 / 2368 (0.89%) 23	
Diabetes mellitus subjects affected / exposed occurrences (all)	23 / 2368 (0.97%) 23	40 / 2368 (1.69%) 40	
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	2 / 2368 (0.08%) 2	
Diabetic metabolic decompensation subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Dyslipidaemia subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	

occurrences (all)	3	1
Electrolyte imbalance		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Fluid overload		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Fluid retention		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Folate deficiency		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Glucose tolerance impaired		
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)
occurrences (all)	3	1
Gout		
subjects affected / exposed	15 / 2368 (0.63%)	18 / 2368 (0.76%)
occurrences (all)	16	21
Hypercalcaemia		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Hypercholesterolaemia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Hyperglycaemia		
subjects affected / exposed	8 / 2368 (0.34%)	5 / 2368 (0.21%)
occurrences (all)	8	5
Hyperkalaemia		
subjects affected / exposed	30 / 2368 (1.27%)	35 / 2368 (1.48%)
occurrences (all)	34	39
Hyperlipidaemia		
subjects affected / exposed	1 / 2368 (0.04%)	5 / 2368 (0.21%)
occurrences (all)	1	5
Hypernatraemia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

occurrences (all)	0	1
Hyperphosphataemia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Hypertriglyceridaemia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Hyperuricaemia		
subjects affected / exposed	8 / 2368 (0.34%)	18 / 2368 (0.76%)
occurrences (all)	8	19
Hypervolaemia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hypoalbuminaemia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hypocalcaemia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hypoglycaemia		
subjects affected / exposed	13 / 2368 (0.55%)	24 / 2368 (1.01%)
occurrences (all)	17	27
Hypokalaemia		
subjects affected / exposed	16 / 2368 (0.68%)	19 / 2368 (0.80%)
occurrences (all)	18	23
Hypomagnesaemia		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Hyponatraemia		
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)
occurrences (all)	4	3
Hypophosphataemia		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Hypovolaemia		
subjects affected / exposed	32 / 2368 (1.35%)	21 / 2368 (0.89%)

occurrences (all)	34	22	
Iron deficiency			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Magnesium deficiency			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Metabolic acidosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Polydipsia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Postprandial hypoglycaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Type 2 diabetes mellitus			
subjects affected / exposed	36 / 2368 (1.52%)	48 / 2368 (2.03%)	
occurrences (all)	36	48	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	63 / 2368 (2.66%)	76 / 2368 (3.21%)	
occurrences (all)	84	100	
Abdominal sepsis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Abscess limb			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Acarodermatitis			

subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Acute sinusitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Arthritis infective		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Appendicitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Atypical pneumonia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Bacteraemia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Bacterial infection		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Balanitis candida		
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)
occurrences (all)	7	0
Bronchitis		
subjects affected / exposed	22 / 2368 (0.93%)	23 / 2368 (0.97%)
occurrences (all)	23	24
Body tinea		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Bronchitis bacterial		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Candida infection		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Bronchitis viral		

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cellulitis		
subjects affected / exposed	9 / 2368 (0.38%)	14 / 2368 (0.59%)
occurrences (all)	11	14
Clostridium difficile infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Chronic sinusitis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Conjunctivitis		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Cystitis		
subjects affected / exposed	6 / 2368 (0.25%)	12 / 2368 (0.51%)
occurrences (all)	7	13
Dacryocystitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dengue fever		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Dermatitis infected		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Diverticulitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Empyema		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Erysipelas		
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)
occurrences (all)	3	6
Epiglottitis		

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Eye infection bacterial		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Fungal balanitis		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Fungal infection		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Furuncle		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Gastroenteritis		
subjects affected / exposed	5 / 2368 (0.21%)	12 / 2368 (0.51%)
occurrences (all)	5	12
Gastroenteritis adenovirus		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Gastroenteritis viral		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Genital infection		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Genital infection fungal		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Gingivitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Groin infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Helicobacter infection		

subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Hepatitis B		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hepatitis C		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Herpes simplex		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Herpes zoster		
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)
occurrences (all)	2	7
Hordeolum		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Infected bite		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Infected dermal cyst		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Infected skin ulcer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Infection		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Influenza		
subjects affected / exposed	22 / 2368 (0.93%)	18 / 2368 (0.76%)
occurrences (all)	23	20

Klebsiella infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Labyrinthitis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Localised infection		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	2	4
Lower respiratory tract infection		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Lung abscess		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Lung infection		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Lyme disease		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Nail bed infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Omphalitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Onychomycosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Ophthalmic herpes zoster		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Oral candidiasis		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2

Orchitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Osteomyelitis		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Otitis externa		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Otitis media		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Otitis media chronic		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Paronychia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	2
Pathogen resistance		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Penile infection		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Periodontitis		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences (all)	2	4
Peritonitis		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Pharyngitis		
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)
occurrences (all)	3	6
Pharyngitis streptococcal		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2

Pneumonia		
subjects affected / exposed	28 / 2368 (1.18%)	30 / 2368 (1.27%)
occurrences (all)	28	32
Post procedural infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Postoperative wound infection		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Pulpitis dental		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Pyelonephritis		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Pyelonephritis chronic		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Respiratory tract infection		
subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)
occurrences (all)	7	3
Respiratory tract infection viral		
subjects affected / exposed	7 / 2368 (0.30%)	6 / 2368 (0.25%)
occurrences (all)	10	10
Rhinitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Septic embolus		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Septic shock		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Sialoadenitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0

Sinusitis		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Skin infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Staphylococcal infection		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Tinea pedis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Tonsillitis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Tooth infection		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Tracheitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Tracheobronchitis		
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)
occurrences (all)	4	2
Upper respiratory tract infection		
subjects affected / exposed	15 / 2368 (0.63%)	15 / 2368 (0.63%)
occurrences (all)	15	16
Urinary tract infection		
subjects affected / exposed	34 / 2368 (1.44%)	31 / 2368 (1.31%)
occurrences (all)	40	40
Urinary tract infection enterococcal		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Urosepsis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0

Viral infection			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Viral pharyngitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Viral sinusitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Vulvovaginal mycotic infection			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	6	0	
Wound infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 October 2017	Amendment #2 included expanding the adverse event of interest category of amputations to also include: AEs leading to a risk for lower limb amputations ("preceding events"). This AE of interest was added based on discussion with regulatory authorities.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported