

**Clinical trial results:**

A Phase III, multicentre, international, randomised, parallel group, double blind cardiovascular safety study of BI 10773 (10 mg and 25 mg administered orally once daily) compared to usual care in type 2 diabetes mellitus (T2DM) patients with increased cardiovascular risk

Summary

EudraCT number	2009-016178-33
Trial protocol	NL DK ES BE FR IT HU PT GB AT GR PL EE CZ
Global end of trial date	13 April 2015

Results information

Result version number	v1 (current)
This version publication date	29 April 2016
First version publication date	29 April 2016

Trial information**Trial identification**

Sponsor protocol code	1245.25
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01131676
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 800 2430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 800 2430127, clintriage.rdg@boehringer-ingelheim.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	13 August 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 April 2015
Global end of trial reached?	Yes
Global end of trial date	13 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this event driven study is to determine non inferiority (non inferiority margin of 1.3) of the treatment with two pooled doses (10mg q.d and 25 mg q.d.) of BI 10773 versus placebo on the composite of 3 Major Adverse Cardiovascular Events (MACE): cardiovascular death, non fatal stroke and nonfatal myocardial infarction in patients with type 2 diabetes mellitus and increased cardiovascular risk.

Protection of trial subjects:

Monitoring of all patients was performed in accordance with protocol. All subjects were free to withdraw at any time for any reason given.

Background therapy:

Standard care therapy for type 2 diabetes and cardiovascular disease .

Evidence for comparator: -

Actual start date of recruitment	26 August 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 41
Country: Number of subjects enrolled	Canada: 246
Country: Number of subjects enrolled	New Zealand: 25
Country: Number of subjects enrolled	United States: 2352
Country: Number of subjects enrolled	Hong Kong: 63
Country: Number of subjects enrolled	India: 280
Country: Number of subjects enrolled	Indonesia: 71
Country: Number of subjects enrolled	Japan: 103
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 494
Country: Number of subjects enrolled	Malaysia: 322
Country: Number of subjects enrolled	Philippines: 366
Country: Number of subjects enrolled	Singapore: 34
Country: Number of subjects enrolled	Sri Lanka: 113
Country: Number of subjects enrolled	Taiwan: 223
Country: Number of subjects enrolled	Thailand: 124
Country: Number of subjects enrolled	Argentina: 395
Country: Number of subjects enrolled	Brazil: 909
Country: Number of subjects enrolled	Colombia: 163

Country: Number of subjects enrolled	Mexico: 140
Country: Number of subjects enrolled	Peru: 244
Country: Number of subjects enrolled	South Africa: 563
Country: Number of subjects enrolled	Austria: 216
Country: Number of subjects enrolled	Belgium: 222
Country: Number of subjects enrolled	Croatia: 220
Country: Number of subjects enrolled	Czech Republic: 26
Country: Number of subjects enrolled	Denmark: 144
Country: Number of subjects enrolled	Estonia: 52
Country: Number of subjects enrolled	France: 144
Country: Number of subjects enrolled	Georgia: 196
Country: Number of subjects enrolled	Greece: 135
Country: Number of subjects enrolled	Hungary: 318
Country: Number of subjects enrolled	Israel: 172
Country: Number of subjects enrolled	Italy: 258
Country: Number of subjects enrolled	Netherlands: 171
Country: Number of subjects enrolled	Norway: 131
Country: Number of subjects enrolled	Poland: 312
Country: Number of subjects enrolled	Portugal: 272
Country: Number of subjects enrolled	Romania: 203
Country: Number of subjects enrolled	Russian Federation: 437
Country: Number of subjects enrolled	Spain: 298
Country: Number of subjects enrolled	Ukraine: 190
Country: Number of subjects enrolled	United Kingdom: 143
Worldwide total number of subjects	11531
EEA total number of subjects	3265

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)	6419
From 65 to 84 years	5060
85 years and over	52

Subject disposition

Recruitment

Recruitment details:

Patients randomised to treatments Placebo, Empagliflozin 10 mg, Empagliflozin 25 mg in a 1:1:1 ratio. Age for one subject was missing, since EudraCT does not support missing category, the same subject is considered under 18-64 age-group.

Pre-assignment

Screening details:

All subjects were screened for eligibility considering the protocol defined inclusion/exclusion criteria to participate in the trial.

Period 1

Period 1 title	Discontinuation from treatment
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

Randomisation stratified by: BMI at randomisation (<30 or ≥ 30 kg/m²), HbA1c at screening ($<8.5\%$ or $\geq 8.5\%$); geographical region (North America including Australia and New Zealand, Latin America, Europe, Africa, Asia); renal function at screening (normal: $\text{eGFR} \geq 90$ mL/min, mild impairment: $60 \text{ mL/min} \leq \text{eGFR} \leq 89$ mL/min, moderate impairment: $30 \text{ mL/min} \leq \text{eGFR} \leq 59$ mL/min).

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily). 4 subjects randomised to Placebo were not treated. Although actual number of subjects started is 2337, 2333 were reported to follow the primary analysis set.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily).

Arm title	Empagliflozin 10 mg
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Arm description:

Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily). 2 subjects randomised to Empagliflozin 10 mg were not treated. Although actual number of subjects started is 2347, 2345 were reported to follow the primary analysis set.

Arm type	Experimental
Investigational medicinal product name	Empagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily)

Arm title	Empagliflozin 25 mg
Arm description:	
Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily). 2 subjects randomised to Empagliflozin 25 mg were not treated. Although actual number of subjects started is 2344, 2342 were reported to follow the primary analysis set.	
Arm type	Experimental
Investigational medicinal product name	Empagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily)

Number of subjects in period 1^[1]	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg
Started	2333	2345	2342
Completed	1650	1790	1800
Not completed	683	555	542
Lack of efficacy	11	1	-
Adverse event, serious fatal	102	89	71
Other than those specified	162	142	125
Adverse event, non-fatal	201	178	202
Refusal to continue, not due to AE	172	118	122
Non compliant with protocol	15	15	12
Study drug stopped, reason missing	5	3	4
Lost to follow-up	15	9	6

Notes:

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

Justification: Baseline characteristics are based on patients who were randomised after successfully completing the screening period and received at least one of the trial medication.

Period 2

Period 2 title	Discontinuation from study (Treated set)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Arms

Are arms mutually exclusive?	No
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Arm title	Placebo
Arm description: Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily)	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily)	
Arm title	Empagliflozin 10 mg
Arm description: Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily)	
Arm type	Experimental
Investigational medicinal product name	Empagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily)	
Arm title	Empagliflozin 25 mg
Arm description: Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily)	
Arm type	Experimental
Investigational medicinal product name	Empagliflozin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily)	

Number of subjects in period 2	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg
Started	2333	2345	2342
Final vital status (VS) available	2316	2324	2327
Completed	2266	2264	2279
Not completed	67	81	63
Site closure: Final VS available	20	21	19
Site closure:Final VS not available (NA)	5	9	7
Lost to FU for 3P-MACE:Final VS NA	4	4	2
Consent withdrawn: Final VS available	23	35	25
Consent withdrawn:Final VS not available	8	6	5

Lost to FU for 3PMACE:Final VS available	7	6	5
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Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily). 4 subjects randomised to Placebo were not treated. Although actual number of subjects started is 2337, 2333 were reported to follow the primary analysis set.	
Reporting group title	Empagliflozin 10 mg
Reporting group description:	
Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily). 2 subjects randomised to Empagliflozin 10 mg were not treated. Although actual number of subjects started is 2347, 2345 were reported to follow the primary analysis set.	
Reporting group title	Empagliflozin 25 mg
Reporting group description:	
Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily). 2 subjects randomised to Empagliflozin 25 mg were not treated. Although actual number of subjects started is 2344, 2342 were reported to follow the primary analysis set.	

Reporting group values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg
Number of subjects	2333	2345	2342
Age categorical			
Units: Subjects			

Age Continuous			
Treated set (TS): Consists of all randomised patients who received at least 1 dose of study medication. Patients were assigned to treatment groups according to the randomisation scheme.			
Units: years			
arithmetic mean	63.2	63	63.2
standard deviation	± 8.8	± 8.6	± 8.6
Gender, Male/Female			
Units: participants			
Female	653	692	659
Male	1680	1653	1683

Reporting group values	Total		
Number of subjects	7020		
Age categorical			
Units: Subjects			

Age Continuous			
Treated set (TS): Consists of all randomised patients who received at least 1 dose of study medication. Patients were assigned to treatment groups according to the randomisation scheme.			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: participants			
Female	2004		
Male	5016		

Subject analysis sets

Subject analysis set title	All Empagliflozin
Subject analysis set type	Full analysis

Subject analysis set description:

Patients who received either 10 mg or 25 mg of empagliflozin were pooled into a common empagliflozin treatment group.

Reporting group values	All Empagliflozin		
Number of subjects	4687		
Age categorical			
Units: Subjects			

Age Continuous			
Treated set (TS): Consists of all randomised patients who received at least 1 dose of study medication. Patients were assigned to treatment groups according to the randomisation scheme.			
Units: years			
arithmetic mean	63.1		
standard deviation	± 8.6		
Gender, Male/Female			
Units: participants			
Female	1351		
Male	3336		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily). 4 subjects randomised to Placebo were not treated. Although actual number of subjects started is 2337, 2333 were reported to follow the primary analysis set.	
Reporting group title	Empagliflozin 10 mg
Reporting group description: Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily). 2 subjects randomised to Empagliflozin 10 mg were not treated. Although actual number of subjects started is 2347, 2345 were reported to follow the primary analysis set.	
Reporting group title	Empagliflozin 25 mg
Reporting group description: Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily). 2 subjects randomised to Empagliflozin 25 mg were not treated. Although actual number of subjects started is 2344, 2342 were reported to follow the primary analysis set.	
Reporting group title	Placebo
Reporting group description: Oral administration of Placebo matching empagliflozin 10 mg or 25 mg (1 tablet once daily)	
Reporting group title	Empagliflozin 10 mg
Reporting group description: Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily)	
Reporting group title	Empagliflozin 25 mg
Reporting group description: Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily)	
Subject analysis set title	All Empagliflozin
Subject analysis set type	Full analysis
Subject analysis set description: Patients who received either 10 mg or 25 mg of empagliflozin were pooled into a common empagliflozin treatment group.	

Primary: Time to the first occurrence of any of the following adjudicated components of the primary composite endpoint (3-point MACE): CV death (including fatal stroke and fatal MI), non-fatal MI (excluding silent MI), and non-fatal stroke.

End point title	Time to the first occurrence of any of the following adjudicated components of the primary composite endpoint (3-point MACE): CV death (including fatal stroke and fatal MI), non-fatal MI (excluding silent MI), and non-fatal stroke.
End point description: Time to the first occurrence of any of the following adjudicated components of the primary composite endpoint (3-point major adverse cardiovascular events (MACE)): cardiovascular (CV) death (including fatal stroke and fatal myocardial infarction (MI)), non-fatal MI (excluding silent MI), and non-fatal stroke. Percentage of patients with the event are presented.	
End point type	Primary
End point timeframe: From randomisation to individual end of observation, up to 4.6 years	

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2333 ^[1]	2345 ^[2]	2342 ^[3]	4687 ^[4]
Units: percentage of participants				
number (not applicable)	12.1	10.4	10.5	10.5

Notes:

[1] - TS (evaluable cases)

[2] - TS (evaluable cases)

[3] - TS (evaluable cases)

[4] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Primary objective was to establish the non-inferiority of All empagliflozin relative to placebo for time to first 3-point MACE. A 4-step hierarchical testing strategy was followed for the non-inferiority test of the primary endpoint and then the key secondary endpoint, each at a margin of 1.3, followed by test of superiority of primary and key secondary endpoints.

Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	7020
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
P-value	< 0.0001 ^[6]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95.02 %
sides	2-sided
lower limit	0.74
upper limit	0.99

Notes:

[5] - The non-inferiority margin was chosen as 1.3 based on Food and Drug Administration (FDA) Guidance for Industry – Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes .

[6] - One-sided test with alpha = 0.0249.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Statistical analysis title	Statistical Analysis 2
Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	7020
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0382 ^[7]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.86
Confidence interval	
level	95.02 %

sides	2-sided
lower limit	0.74
upper limit	0.99

Notes:

[7] - Two-sided test with $\alpha=0.0498$.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Secondary: Percentage of participants with composite of all events adjudicated (4-point MACE):CV death (including fatal stroke and fatal MI), non-fatal MI (excluding silent MI), non-fatal stroke and hospitalization for unstable angina pectoris

End point title	Percentage of participants with composite of all events adjudicated (4-point MACE):CV death (including fatal stroke and fatal MI), non-fatal MI (excluding silent MI), non-fatal stroke and hospitalization for unstable angina pectoris
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End point description:

The composite of all events adjudicated (4-point MACE): cardiovascular death (including fatal stroke and fatal myocardial infarction), non-fatal myocardial infarction (excluding silent MI), non-fatal stroke and hospitalization for unstable angina pectoris. This is a key secondary endpoint of the trial.

Percentage of patients with the event are presented.

End point type	Secondary
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End point timeframe:

From randomisation to individual end of observation, up to 4.6 years

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2333 ^[8]	2345 ^[9]	2342 ^[10]	4687 ^[11]
Units: percentage of participants				
number (not applicable)	14.3	12.8	12.8	12.8

Notes:

[8] - TS (evaluable cases)

[9] - TS (evaluable cases)

[10] - TS (evaluable cases)

[11] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

A 4-step hierarchical testing strategy was followed for the non-inferiority test of the primary endpoint and then the key secondary endpoint, each at a margin of 1.3, followed by test of superiority of primary and key secondary endpoints.

Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	7020
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[12]
P-value	< 0.0001 ^[13]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	

level	95.02 %
sides	2-sided
lower limit	0.78
upper limit	1.01

Notes:

[12] - The non-inferiority margin was chosen as 1.3 based on Food and Drug Administration (FDA) Guidance for Industry – Diabetes Mellitus – Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes

[13] - One-sided test with $\alpha = 0.0249$.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Statistical analysis title	Statistical analysis 2
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Statistical analysis description:

A 4-step hierarchical testing strategy was followed for the non-inferiority test of the primary endpoint and then the key secondary endpoint, each at a margin of 1.3, followed by test of superiority of primary and key secondary endpoints.

Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	7020
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.0795 ^[14]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95.02 %
sides	2-sided
lower limit	0.78
upper limit	1.01

Notes:

[14] - Two-sided test with $\alpha=0.0498$.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Secondary: Percentage of participants with silent MI

End point title	Percentage of participants with silent MI
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End point description:

Silent MI; defined as presence in the ECG of:

- Any Q-wave in leads V2-V3 ≥ 0.02 seconds or QS complex in leads V2 and V3
- Q-wave ≥ 0.03 seconds and ≥ 0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V6; V4-V6; II, III, and aVF)
- R-wave ≥ 0.04 seconds in V1-V2 and R/S ≥ 1 with a concordant positive T-wave in the absence of a conduction defect.

It was also required that there had been no adjudicated and confirmed event of either acute MI, hospitalisation for unstable angina, coronary revascularisation procedures or stent thrombosis following randomisation up to and including the date of the specified ECG measurement.

Percentage of patients with the event are presented.

End point type	Secondary
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End point timeframe:

From randomisation to individual end of observation, up to 4.6 years

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1211 ^[15]	1174 ^[16]	1204 ^[17]	2378 ^[18]
Units: percentage of participants				
number (not applicable)	1.2	1.6	1.6	1.6

Notes:

[15] - TS (evaluable cases)

[16] - TS (evaluable cases)

[17] - TS (evaluable cases)

[18] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	3589
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4172 ^[19]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	1.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.33

Notes:

[19] - Two-sided test with alpha = 0.05.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo

Secondary: Percentage of participants with heart failure requiring hospitalisation (adjudicated)

End point title	Percentage of participants with heart failure requiring hospitalisation (adjudicated)
End point description:	
	Heart failure requiring hospitalisation (adjudicated). Percentage of patients with the event are presented.
End point type	Secondary
End point timeframe:	
	From randomisation to individual end of observation, up to 4.6 years

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2333 ^[20]	2345 ^[21]	2342 ^[22]	4687 ^[23]
Units: percentage of participants				
number (not applicable)	4.1	2.6	2.8	2.7

Notes:

[20] - TS (evaluable cases)

[21] - TS (evaluable cases)

[22] - TS (evaluable cases)

[23] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	7020
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0017 ^[24]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.85

Notes:

[24] - Two-sided test with alpha = 0.05.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Secondary: Percentage of participants with new onset albuminuria

End point title	Percentage of participants with new onset albuminuria
End point description:	
New onset albuminuria defined as urine albumin / creatinine ratio (UACR) ≥ 30 mg/g.	
Percentage of patients with the event are presented.	
End point type	Secondary
End point timeframe:	
From randomisation to individual end of observation, up to 4.6 years	

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1374 ^[25]	1403 ^[26]	1376 ^[27]	2779 ^[28]
Units: percentage of participants				
number (not applicable)	51.2	51.5	51.5	51.5

Notes:

[25] - TS (evaluable cases)

[26] - TS (evaluable cases)

[27] - TS (evaluable cases)

[28] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	4153
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.2547 [29]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.04

Notes:

[29] - Two-sided test with alpha = 0.05.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo

Secondary: Percentage of participants with new onset macroalbuminuria

End point title	Percentage of participants with new onset macroalbuminuria
End point description:	
New onset macroalbuminuria defined as UACR >300 mg/g. Percentage of patients with the event are presented.	
End point type	Secondary
End point timeframe:	
From randomisation to individual end of observation, up to 4.6 years	

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2033 ^[30]	2037 ^[31]	2054 ^[32]	4091 ^[33]
Units: percentage of participants				
number (not applicable)	16.2	10.9	11.5	11.2

Notes:

[30] - TS (evaluable cases)

[31] - TS (evaluable cases)

[32] - TS (evaluable cases)

[33] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	6124
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001 ^[34]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.72

Notes:

[34] - Two-sided test with alpha = 0.05.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Secondary: Percentage of participants with composite microvascular outcome

End point title	Percentage of participants with composite microvascular outcome
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End point description:

Composite microvascular outcome defined as:

- Initiation of retinal photocoagulation
- Vitreous haemorrhage
- Diabetes-related blindness, or
- New or worsening nephropathy defined as:
 - New onset of macroalbuminuria; or
 - Doubling of serum creatinine level accompanied by an eGFR (based on modification of diet in renal disease (MDRD) formula) ≤ 45 mL/min/1.73m²; or
 - Initiation of continuous renal replacement therapy, or
 - Death due to renal disease.

Percentage of patients with the event are presented.

End point type	Secondary
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End point timeframe:

From randomisation to individual end of observation, up to 4.6 years

End point values	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg	All Empagliflozin
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	2068 ^[35]	2057 ^[36]	2075 ^[37]	4132 ^[38]
Units: percentage of participants				
number (not applicable)	20.5	13.9	14.1	14

Notes:

[35] - TS (evaluable cases)

[36] - TS (evaluable cases)

[37] - TS (evaluable cases)

[38] - TS (evaluable cases)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v All Empagliflozin
Number of subjects included in analysis	6200
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001 ^[39]
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.7

Notes:

[39] - Two-sided test with alpha = 0.05.

Cox proportional hazards model with factors for treatment, age, gender, categorised BMI, HbA1c, eGFR and geographical region.

All Empagliflozin divided by Placebo.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs, serious and non-serious, occurring during the course of the clinical trial (adverse events up until treatment stop + 7 days); Up to 4.6 years

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description:

Oral administration of Placebo matching empagliflozin 10 mg and 25 mg (1 tablet once daily)

Reporting group title	Empagliflozin 10 mg
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Reporting group description:

Oral administration of Empagliflozin 10 mg (BI 10773) film coated tablets (1 tablet once daily)

Reporting group title	Empagliflozin 25 mg
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Reporting group description:

Oral administration of Empagliflozin 25 mg (BI 10773) film coated tablets (1 tablet once daily)

Reporting group title	All Empagliflozin
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Reporting group description:

Patients who received either 10 mg or 25 mg of empagliflozin were pooled into a common empagliflozin treatment group for the purposes of the primary analysis.

Serious adverse events	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	988 / 2333 (42.35%)	876 / 2345 (37.36%)	913 / 2342 (38.98%)
number of deaths (all causes)	119	97	79
number of deaths resulting from adverse events	2	3	1
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia postoperative			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Avulsion fracture			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	2 / 2333 (0.09%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical poisoning			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac procedure complication			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	4 / 2333 (0.17%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery restenosis			
subjects affected / exposed	4 / 2333 (0.17%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis postoperative			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	16 / 2333 (0.69%)	9 / 2345 (0.38%)	16 / 2342 (0.68%)
occurrences causally related to treatment / all	0 / 16	1 / 9	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femoral neck fracture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	3 / 2333 (0.13%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal anastomotic complication			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Graft thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			

subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gun shot wound			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal anastomosis complication			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney rupture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Open fracture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital contusion			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periprosthetic fracture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peripheral artery restenosis			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perirenal haematoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post laminectomy syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discomfort			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	6 / 2333 (0.26%)	6 / 2345 (0.26%)	9 / 2342 (0.38%)

occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Rib fracture			
subjects affected / exposed	6 / 2333 (0.26%)	4 / 2345 (0.17%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin abrasion			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	7 / 2333 (0.30%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tongue injury			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic renal injury			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft occlusion			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	2 / 2333 (0.09%)	3 / 2345 (0.13%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiogram			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to	0 / 1	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiogram normal			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriogram coronary			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biopsy lung			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood calcium decreased			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase MB increased			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose fluctuation			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood magnesium decreased			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood potassium increased			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure orthostatic decreased			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood urea increased			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
C-reactive protein increased subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac murmur subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac stress test abnormal subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheterisation cardiac subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave inversion subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate irregular subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatic enzyme increased subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen consumption increased subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical examination subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic specific antigen increased subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scan myocardial perfusion abnormal subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Smear cervix abnormal subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	10 / 2333 (0.43%)	10 / 2345 (0.43%)	14 / 2342 (0.60%)
occurrences causally related to treatment / all	0 / 10	0 / 10	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Acute myocardial infarction			
subjects affected / exposed	42 / 2333 (1.80%)	32 / 2345 (1.36%)	48 / 2342 (2.05%)
occurrences causally related to treatment / all	2 / 46	2 / 33	2 / 56
deaths causally related to treatment / all	0 / 7	0 / 3	0 / 6
Angina unstable			
subjects affected / exposed	87 / 2333 (3.73%)	82 / 2345 (3.50%)	73 / 2342 (3.12%)
occurrences causally related to treatment / all	3 / 106	13 / 101	3 / 89
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	32 / 2333 (1.37%)	36 / 2345 (1.54%)	42 / 2342 (1.79%)
occurrences causally related to	2 / 33	2 / 40	3 / 45

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	14 / 2333 (0.60%)	25 / 2345 (1.07%)	12 / 2342 (0.51%)
occurrences causally related to treatment / all	0 / 14	1 / 27	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	2 / 2333 (0.09%)	5 / 2345 (0.21%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Atrial flutter			
subjects affected / exposed	5 / 2333 (0.21%)	7 / 2345 (0.30%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block first degree			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	11 / 2333 (0.47%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	1 / 11	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block bilateral			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	12 / 2333 (0.51%)	6 / 2345 (0.26%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 12	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 10	0 / 2	0 / 2

Bundle branch block right			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac asthma			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac disorder			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	55 / 2333 (2.36%)	42 / 2345 (1.79%)	24 / 2342 (1.02%)
occurrences causally related to treatment / all	1 / 67	3 / 50	1 / 25
deaths causally related to treatment / all	0 / 5	0 / 3	0 / 1
Cardiac failure acute			
subjects affected / exposed	9 / 2333 (0.39%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac failure chronic			
subjects affected / exposed	0 / 2333 (0.00%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure high output			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	45 / 2333 (1.93%)	30 / 2345 (1.28%)	35 / 2342 (1.49%)
occurrences causally related to treatment / all	0 / 63	2 / 39	1 / 48
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Cardiomyopathy			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	6 / 2333 (0.26%)	5 / 2345 (0.21%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 4	0 / 4	0 / 2
Cardiogenic shock			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Cardiopulmonary failure			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Cardiovascular insufficiency			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiorenal syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular disorder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	46 / 2333 (1.97%)	21 / 2345 (0.90%)	29 / 2342 (1.24%)
occurrences causally related to treatment / all	0 / 48	0 / 26	1 / 33
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	6 / 2333 (0.26%)	3 / 2345 (0.13%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery insufficiency			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	5 / 2333 (0.21%)	5 / 2345 (0.21%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 6	1 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diastolic dysfunction			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracardiac thrombus			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left atrial dilatation			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microvascular coronary artery disease			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	15 / 2333 (0.64%)	5 / 2345 (0.21%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 16	1 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	47 / 2333 (2.01%)	50 / 2345 (2.13%)	44 / 2342 (1.88%)
occurrences causally related to treatment / all	3 / 48	8 / 55	1 / 48
deaths causally related to treatment / all	0 / 11	0 / 12	0 / 9
Myocarditis			

subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal arrhythmia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pericardial cyst			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary muscle disorder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postinfarction angina			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Silent myocardial infarction			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 1	2 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrhythmia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	4 / 2333 (0.17%)	5 / 2345 (0.21%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	6 / 2333 (0.26%)	5 / 2345 (0.21%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systolic dysfunction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	5 / 2333 (0.21%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia paroxysmal			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trifascicular block			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ventricular arrhythmia			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	8 / 2333 (0.34%)	2 / 2345 (0.09%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 9	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital anomalies of ear ossicles			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosi			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyloric stenosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 2333 (0.51%)	8 / 2345 (0.34%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	1 / 12	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypereosinophilic syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic anaemia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocoagulable state			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnesia			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autonomic neuropathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balance disorder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain stem infarction			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem stroke			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem ischaemia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Carotid arteriosclerosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery disease			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery occlusion			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	10 / 2333 (0.43%)	7 / 2345 (0.30%)	12 / 2342 (0.51%)
occurrences causally related to treatment / all	0 / 10	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central nervous system inflammation			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery occlusion			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery stenosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ataxia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	7 / 2333 (0.30%)	7 / 2345 (0.30%)	11 / 2342 (0.47%)
occurrences causally related to treatment / all	0 / 8	0 / 7	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	31 / 2333 (1.33%)	46 / 2345 (1.96%)	37 / 2342 (1.58%)
occurrences causally related to treatment / all	1 / 34	0 / 47	0 / 39
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 2
Cerebral ischaemia			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical cord compression			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cervical myelopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complex partial seizures			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coordination abnormal			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diabetic neuropathy			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dizziness				
subjects affected / exposed	5 / 2333 (0.21%)	8 / 2345 (0.34%)	5 / 2342 (0.21%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Dysarthria				
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Embolitic cerebral infarction				
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Embolitic stroke				
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Encephalopathy				
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Epilepsy				
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Generalised tonic-clonic seizure				
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Guillain-Barre syndrome				
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Haemorrhage intracranial				
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)	

occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	4 / 2333 (0.17%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Headache			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnic coma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkinesia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive encephalopathy subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic coma subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paralysis subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke subjects affected / exposed	22 / 2333 (0.94%)	18 / 2345 (0.77%)	20 / 2342 (0.85%)
occurrences causally related to treatment / all	1 / 26	1 / 18	1 / 24
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1

Lacunar infarction			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mononeuritis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasticity			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis transverse			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve root compression			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroleptic malignant syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Piriformis syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Radiculopathy			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	4 / 2333 (0.17%)	7 / 2345 (0.30%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory disturbance			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal epidural haematoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	3 / 2333 (0.13%)	3 / 2345 (0.13%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Spondylitic myelopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	8 / 2333 (0.34%)	9 / 2345 (0.38%)	18 / 2342 (0.77%)

occurrences causally related to treatment / all	0 / 8	2 / 9	1 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural hygroma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic cerebral infarction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Transient ischaemic attack			
subjects affected / exposed	23 / 2333 (0.99%)	23 / 2345 (0.98%)	30 / 2342 (1.28%)
occurrences causally related to treatment / all	1 / 26	0 / 24	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery dissection			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral artery stenosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	3 / 2333 (0.13%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paresis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract cortical			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	9 / 2333 (0.39%)	13 / 2345 (0.55%)	11 / 2342 (0.47%)
occurrences causally related to treatment / all	0 / 9	0 / 16	0 / 13

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exfoliation syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic retinopathy			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal degeneration			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular oedema			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Papilloedema			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal tear			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 2333 (0.00%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinoschisis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual acuity reduced			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous opacities			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness unilateral			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerumen impaction			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinnitus			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden hearing loss			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tympanic membrane perforation			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	7 / 2333 (0.30%)	2 / 2345 (0.09%)	9 / 2342 (0.38%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	6 / 2333 (0.26%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to	0 / 6	0 / 0	0 / 4

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	5 / 2333 (0.21%)	5 / 2345 (0.21%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Abdominal hernia obstructive			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bezoar			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	4 / 2333 (0.17%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diabetic gastroparesis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gastropathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	6 / 2333 (0.26%)	6 / 2345 (0.26%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epigastric discomfort			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive duodenitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastritis erosive			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenal ulcer			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	9 / 2333 (0.39%)	4 / 2345 (0.17%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	5 / 2333 (0.21%)	7 / 2345 (0.30%)	3 / 2342 (0.13%)

occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival bleeding			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	3 / 2333 (0.13%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	3 / 2333 (0.13%)	5 / 2345 (0.21%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	5 / 2333 (0.21%)	1 / 2345 (0.04%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Intestinal perforation			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 2333 (0.00%)	5 / 2345 (0.21%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised intraabdominal fluid collection			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar hernia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			

subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 2333 (0.09%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	4 / 2333 (0.17%)	3 / 2345 (0.13%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis relapsing			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small intestinal obstruction			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress ulcer			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	2 / 2333 (0.09%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 2333 (0.09%)	3 / 2345 (0.13%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Albuminuria			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute prerenal failure			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	32 / 2333 (1.37%)	26 / 2345 (1.11%)	19 / 2342 (0.81%)
occurrences causally related to treatment / all	3 / 34	0 / 27	4 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neck sclerosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder outlet obstruction			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			

subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis glandularis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic nephropathy			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	4 / 2333 (0.17%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower urinary tract symptoms			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nephritis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microalbuminuria			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	3 / 2333 (0.13%)	3 / 2345 (0.13%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive uropathy			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyuria			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery arteriosclerosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	10 / 2333 (0.43%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 11	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal tubular necrosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stress urinary incontinence			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	2 / 2333 (0.09%)	4 / 2345 (0.17%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder polyp			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	3 / 2333 (0.13%)	4 / 2345 (0.17%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 5	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cold sweat			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis contact			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic bullosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	12 / 2333 (0.51%)	10 / 2345 (0.43%)	11 / 2342 (0.47%)
occurrences causally related to treatment / all	0 / 14	0 / 10	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to	0 / 0	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythrodermic psoriasis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ingrowing nail			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoplakia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathic ulcer			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pemphigus			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin fibrosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	10 / 2333 (0.43%)	6 / 2345 (0.26%)	11 / 2342 (0.47%)
occurrences causally related to treatment / all	0 / 13	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Skin ulcer haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	9 / 2333 (0.39%)	3 / 2345 (0.13%)	8 / 2342 (0.34%)
occurrences causally related to treatment / all	0 / 9	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone fistula			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dactylitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture delayed union			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fracture nonunion			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty tophus			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc compression			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	10 / 2333 (0.43%)	4 / 2345 (0.17%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower extremity mass			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	3 / 2342 (0.13%)

occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle tightness			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle twitching			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal disorder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myofascial pain syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathic arthropathy			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis deformans			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	15 / 2333 (0.64%)	15 / 2345 (0.64%)	17 / 2342 (0.73%)
occurrences causally related to treatment / all	0 / 16	0 / 16	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomalacia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Osteoporosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic fracture			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	4 / 2333 (0.17%)	3 / 2345 (0.13%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	6 / 2345 (0.26%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	6 / 2333 (0.26%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)

occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis stenosans			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger finger			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to	0 / 0	0 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism primary			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	5 / 2333 (0.21%)	5 / 2345 (0.21%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 5	1 / 5	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	6 / 2333 (0.26%)	3 / 2345 (0.13%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diabetes mellitus inadequate control			
subjects affected / exposed	6 / 2333 (0.26%)	8 / 2345 (0.34%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 8	0 / 3

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic complication			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	14 / 2333 (0.60%)	5 / 2345 (0.21%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	1 / 15	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	5 / 2333 (0.21%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	1 / 5	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypervolaemia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypoglycaemia			
subjects affected / exposed	17 / 2333 (0.73%)	10 / 2345 (0.43%)	9 / 2342 (0.38%)
occurrences causally related to treatment / all	0 / 21	4 / 11	2 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insulin resistance			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipomatosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	3 / 2333 (0.13%)	6 / 2345 (0.26%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of eyelid			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to	0 / 0	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic dysentery			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	3 / 2333 (0.13%)	5 / 2345 (0.21%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerotic gangrene			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone abscess			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	10 / 2333 (0.43%)	5 / 2345 (0.21%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 10	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchopneumonia			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	20 / 2333 (0.86%)	11 / 2345 (0.47%)	17 / 2342 (0.73%)
occurrences causally related to treatment / all	0 / 24	0 / 20	0 / 17
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis gangrenous			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis of male external genital organ			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous larva migrans			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis bacterial			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	6 / 2333 (0.26%)	5 / 2345 (0.21%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetic gangrene			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)

occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	3 / 2333 (0.13%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema infected			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis viral			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	9 / 2333 (0.39%)	8 / 2345 (0.34%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 9	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Furuncle			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder empyema			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	8 / 2333 (0.34%)	10 / 2345 (0.43%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 8	0 / 13	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis				
subjects affected / exposed	15 / 2333 (0.64%)	18 / 2345 (0.77%)	15 / 2342 (0.64%)	
occurrences causally related to treatment / all	0 / 16	1 / 18	2 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Gastroenteritis salmonella				
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Gastroenteritis viral				
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Gastrointestinal infection				
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0	
Gastrointestinal protozoal infection				
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Giardiasis				
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
H1N1 influenza				
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Incision site infection				
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Infected skin ulcer				
subjects affected / exposed	4 / 2333 (0.17%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)	

occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Infectious colitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia gangrenous			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site infection			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fistula infection			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal tuberculosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	5 / 2333 (0.21%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	4 / 2333 (0.17%)	8 / 2345 (0.34%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection bacterial			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mediastinitis			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis streptococcal			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis tuberculous			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal abscess			

subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	5 / 2333 (0.21%)	5 / 2345 (0.21%)	9 / 2342 (0.38%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis acute			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis bacterial			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)

occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	53 / 2333 (2.27%)	41 / 2345 (1.75%)	38 / 2342 (1.62%)
occurrences causally related to treatment / all	0 / 63	0 / 45	0 / 41
deaths causally related to treatment / all	0 / 5	0 / 3	0 / 3
Pneumonia influenzal			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural sepsis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Postoperative wound infection			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic abscess			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary mycosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	6 / 2333 (0.26%)	4 / 2345 (0.17%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	1 / 6	1 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	7 / 2333 (0.30%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pyelonephritis chronic			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salmonellosis			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	5 / 2333 (0.21%)	7 / 2345 (0.30%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 5	0 / 7	1 / 6
deaths causally related to treatment / all	0 / 3	0 / 3	0 / 1
Septic encephalopathy			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	8 / 2333 (0.34%)	2 / 2345 (0.09%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 4	0 / 2	1 / 1
Sinusitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculous pleurisy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	16 / 2333 (0.69%)	13 / 2345 (0.55%)	16 / 2342 (0.68%)
occurrences causally related to treatment / all	4 / 16	6 / 14	3 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection fungal			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	3 / 2333 (0.13%)	6 / 2345 (0.26%)	11 / 2342 (0.47%)
occurrences causally related to treatment / all	0 / 3	2 / 6	4 / 12
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
Vaginal cellulitis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	3 / 2333 (0.13%)	4 / 2345 (0.17%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound sepsis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic arteriosclerosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	4 / 2333 (0.17%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arterial disorder			
subjects affected / exposed	4 / 2333 (0.17%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to	0 / 4	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial occlusive disease			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteritis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	5 / 2333 (0.21%)	3 / 2345 (0.13%)	10 / 2342 (0.43%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic microangiopathy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Embolism arterial			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	5 / 2333 (0.21%)	4 / 2345 (0.17%)	8 / 2342 (0.34%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	10 / 2333 (0.43%)	4 / 2345 (0.17%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 11	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypertensive crisis			
subjects affected / exposed	8 / 2333 (0.34%)	3 / 2345 (0.13%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	9 / 2333 (0.39%)	5 / 2345 (0.21%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery occlusion			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infarction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	2 / 2333 (0.09%)	4 / 2345 (0.17%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	2 / 2333 (0.09%)	3 / 2345 (0.13%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	23 / 2333 (0.99%)	28 / 2345 (1.19%)	30 / 2342 (1.28%)
occurrences causally related to treatment / all	1 / 30	1 / 37	0 / 38
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	6 / 2333 (0.26%)	3 / 2345 (0.13%)	9 / 2342 (0.38%)
occurrences causally related to treatment / all	0 / 9	0 / 3	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral coldness			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	9 / 2333 (0.39%)	4 / 2345 (0.17%)	11 / 2342 (0.47%)
occurrences causally related to treatment / all	0 / 11	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	8 / 2333 (0.34%)	3 / 2345 (0.13%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	1 / 8	0 / 3	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery stenosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Varicose vein			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular calcification			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular insufficiency			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous occlusion			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Angioplasty			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary angioplasty			
subjects affected / exposed	3 / 2333 (0.13%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary arterial stent insertion			

subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery bypass			
subjects affected / exposed	4 / 2333 (0.17%)	3 / 2345 (0.13%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary revascularisation			
subjects affected / exposed	5 / 2333 (0.21%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture treatment			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Percutaneous coronary intervention			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prophylaxis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent placement			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute lymphocytic leukaemia			

subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	2 / 2333 (0.09%)	3 / 2345 (0.13%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Adenoma benign			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anogenital warts			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	16 / 2333 (0.69%)	15 / 2345 (0.64%)	12 / 2342 (0.51%)
occurrences causally related to treatment / all	0 / 18	0 / 17	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basosquamous carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign hepatic neoplasm			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign laryngeal neoplasm			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of adrenal gland			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of bladder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of prostate			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm of thyroid gland subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign pancreatic neoplasm subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign respiratory tract neoplasm subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign uterine neoplasm subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Bladder cancer recurrent subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone cancer			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone giant cell tumour benign			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Breast cancer			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac myxoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholesteatoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer subjects affected / exposed	2 / 2333 (0.09%)	5 / 2345 (0.21%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Colon cancer metastatic subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Colon neoplasm subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrosarcoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Follicular thyroid cancer			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital neoplasm malignant female			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of bone			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemangioma of liver			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic neoplasm			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Hodgkin's disease stage I			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large cell lung cancer			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Laryngeal squamous cell carcinoma subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lipoma subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma subjects affected / exposed	2 / 2333 (0.09%)	5 / 2345 (0.21%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 2
Lung cancer metastatic subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung carcinoma cell type unspecified stage III subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	7 / 2342 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 4
Lung squamous cell carcinoma stage III subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lymphocytic lymphoma subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoproliferative disorder			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	3 / 2333 (0.13%)	5 / 2345 (0.21%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	1 / 3	0 / 5	0 / 5
deaths causally related to treatment / all	1 / 2	0 / 1	0 / 3
Metastases to lung			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to lymph nodes			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to neck			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to pleura			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastasis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastatic malignant melanoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myelodysplastic syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngeal cancer			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Non-Hodgkin's lymphoma stage IV			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Oesophageal carcinoma			

subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
POEMS syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 1
Papillary serous endometrial carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile squamous cell carcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	9 / 2333 (0.39%)	11 / 2345 (0.47%)	9 / 2342 (0.38%)
occurrences causally related to treatment / all	0 / 9	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 2333 (0.00%)	4 / 2345 (0.17%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Prostate cancer recurrent			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 2333 (0.00%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer metastatic			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma stage I subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma stage II subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland neoplasm subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland adenoma subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell carcinoma subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic marginal zone lymphoma subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small cell lung cancer			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	3 / 2333 (0.13%)	6 / 2345 (0.26%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	7 / 2333 (0.30%)	4 / 2345 (0.17%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	3 / 2333 (0.13%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			

subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contrast media allergy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iodine allergy			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Physical assault			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac death			
subjects affected / exposed	3 / 2333 (0.13%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 4	0 / 2
Asthenia			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	4 / 2333 (0.17%)	2 / 2345 (0.09%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	28 / 2333 (1.20%)	32 / 2345 (1.36%)	33 / 2342 (1.41%)
occurrences causally related to treatment / all	0 / 31	1 / 32	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	12 / 2333 (0.51%)	10 / 2345 (0.43%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 12	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 12	0 / 10	0 / 5
Device defective			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device deposit issue			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device difficult to use			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device occlusion			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug ineffective			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drowning			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dysplasia			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)

occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extravasation			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeling abnormal			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site necrosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	3 / 2333 (0.13%)	2 / 2345 (0.09%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Necrobiosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	6 / 2333 (0.26%)	5 / 2345 (0.21%)	15 / 2342 (0.64%)
occurrences causally related to treatment / all	0 / 7	0 / 5	1 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	5 / 2333 (0.21%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oversensing			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pacemaker generated arrhythmia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perforated ulcer			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	5 / 2333 (0.21%)	7 / 2345 (0.30%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyp			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated hernia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent malfunction			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	6 / 2333 (0.26%)	8 / 2345 (0.34%)	5 / 2342 (0.21%)

occurrences causally related to treatment / all	1 / 6	1 / 8	0 / 5
deaths causally related to treatment / all	1 / 6	1 / 8	0 / 5
Sudden cardiac death			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 2
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcer			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anxiety			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	2 / 2333 (0.09%)	3 / 2345 (0.13%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	5 / 2333 (0.21%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rapid eye movements sleep abnormal			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance abuse			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	6 / 2333 (0.26%)	8 / 2345 (0.34%)	10 / 2342 (0.43%)
occurrences causally related to treatment / all	0 / 7	0 / 8	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Endometrial hyperplasia			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrocystic breast disease			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital prolapse			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gynaecomastia			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatism			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal prolapse			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	5 / 2333 (0.21%)	7 / 2345 (0.30%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 1

deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Acute respiratory distress syndrome subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Acute respiratory failure subjects affected / exposed	4 / 2333 (0.17%)	5 / 2345 (0.21%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Allergic sinusitis subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma subjects affected / exposed	6 / 2333 (0.26%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	3 / 2342 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial disorder subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial secretion retention subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchitis chronic			
subjects affected / exposed	0 / 2333 (0.00%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	2 / 2333 (0.09%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	11 / 2333 (0.47%)	6 / 2345 (0.26%)	10 / 2342 (0.43%)
occurrences causally related to treatment / all	0 / 20	0 / 7	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	14 / 2333 (0.60%)	6 / 2345 (0.26%)	9 / 2342 (0.38%)
occurrences causally related to treatment / all	0 / 14	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 2333 (0.04%)	3 / 2345 (0.13%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			

subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 2333 (0.04%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 2333 (0.04%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal haematoma			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranasal cyst			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural fibrosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pleurisy			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	2 / 2333 (0.09%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	4 / 2333 (0.17%)	0 / 2345 (0.00%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary fibrosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Pulmonary hypertension			
subjects affected / exposed	5 / 2333 (0.21%)	1 / 2345 (0.04%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pulmonary oedema			
subjects affected / exposed	5 / 2333 (0.21%)	2 / 2345 (0.09%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary thrombosis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	9 / 2333 (0.39%)	2 / 2345 (0.09%)	4 / 2342 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 0	0 / 0
Sinus disorder			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	4 / 2333 (0.17%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status asthmaticus			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper airway obstruction			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord thickening			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	0 / 2333 (0.00%)	4 / 2345 (0.17%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	4 / 2333 (0.17%)	7 / 2345 (0.30%)	6 / 2342 (0.26%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	4 / 2333 (0.17%)	4 / 2345 (0.17%)	5 / 2342 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to	0 / 2	0 / 0	1 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	7 / 2333 (0.30%)	9 / 2345 (0.38%)	12 / 2342 (0.51%)
occurrences causally related to treatment / all	0 / 7	0 / 9	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder disorder			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	2 / 2333 (0.09%)	2 / 2345 (0.09%)	2 / 2342 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic hepatitis			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 2333 (0.00%)	0 / 2345 (0.00%)	1 / 2342 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post cholecystectomy syndrome			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 2333 (0.00%)	1 / 2345 (0.04%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sphincter of Oddi dysfunction			
subjects affected / exposed	1 / 2333 (0.04%)	0 / 2345 (0.00%)	0 / 2342 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	All Empagliflozin		
Total subjects affected by serious adverse events			
subjects affected / exposed	1789 / 4687 (38.17%)		
number of deaths (all causes)	176		
number of deaths resulting from adverse events	4		
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	1 / 4687 (0.02%)		

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Accident at work				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia postoperative				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Animal bite				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Avulsion fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	1 / 6			
deaths causally related to treatment / all	0 / 0			
Brain contusion				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Back injury				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest injury				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Chemical poisoning				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac procedure complication				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Clavicle fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Coronary artery restenosis				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis postoperative				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Fall				
subjects affected / exposed	25 / 4687 (0.53%)			
occurrences causally related to treatment / all	1 / 25			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fracture displacement				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal anastomotic complication				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Graft thrombosis				

subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Gun shot wound			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	5 / 4687 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	8 / 4687 (0.17%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Injury			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intentional overdose			
subjects affected / exposed	1 / 4687 (0.02%)		

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal anastomosis complication			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney rupture			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ligament sprain			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 2		

deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meniscus injury				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple fractures				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle injury				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple injuries				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Open fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Periorbital contusion				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Pelvic fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Periprosthetic fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery restenosis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Perirenal haematoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post laminectomy syndrome				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural discomfort				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Post procedural haematuria				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pubis fracture				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	15 / 4687 (0.32%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 2		
Rib fracture			
subjects affected / exposed	8 / 4687 (0.17%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Scar			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Seroma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal column injury			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin abrasion			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Splenic rupture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stab wound				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haemorrhage				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon injury				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Thoracic vertebral fracture subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tongue injury subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Traumatic haematoma subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic haemorrhage subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haemorrhage subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic liver injury subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic renal injury subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vascular graft occlusion				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Vascular graft thrombosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular pseudoaneurysm				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			

deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angiogram			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angiogram normal			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anticoagulation drug level above therapeutic			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriogram coronary			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biopsy lung			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood calcium decreased			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase MB increased				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase increased				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Blood glucose fluctuation				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood magnesium decreased				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood potassium increased				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood pressure increased				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Blood pressure orthostatic decreased subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood urea increased subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
C-reactive protein increased subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cardiac murmur subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac stress test abnormal subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Catheterisation cardiac subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ejection fraction decreased subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram T wave inversion subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Haemoglobin decreased				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Heart rate irregular				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test abnormal				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oxygen consumption increased				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Physical examination				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatic specific antigen increased				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Scan myocardial perfusion abnormal				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Smear cervix abnormal			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transaminases increased			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Troponin increased			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Troponin I increased			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
White blood cell count increased			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	24 / 4687 (0.51%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 1		
Acute myocardial infarction			
subjects affected / exposed	80 / 4687 (1.71%)		
occurrences causally related to	4 / 89		

treatment / all				
deaths causally related to treatment / all	0 / 9			
Angina unstable				
subjects affected / exposed	155 / 4687 (3.31%)			
occurrences causally related to treatment / all	16 / 190			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	78 / 4687 (1.66%)			
occurrences causally related to treatment / all	5 / 85			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Aortic valve disease				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	37 / 4687 (0.79%)			
occurrences causally related to treatment / all	1 / 40			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 1			
Atrial flutter				
subjects affected / exposed	11 / 4687 (0.23%)			
occurrences causally related to treatment / all	0 / 11			

deaths causally related to treatment / all	0 / 0			
Atrial tachycardia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial thrombosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block first degree				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bradyarrhythmia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	1 / 6			
deaths causally related to treatment / all	0 / 0			

Bundle branch block bilateral subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest subjects affected / exposed	11 / 4687 (0.23%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 4			
Bundle branch block right subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac asthma subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiac disorder subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure subjects affected / exposed	66 / 4687 (1.41%)			
occurrences causally related to treatment / all	4 / 75			
deaths causally related to treatment / all	0 / 4			
Cardiac failure acute subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 1			
Cardiac failure chronic subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Cardiac failure high output subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive subjects affected / exposed	65 / 4687 (1.39%)		
occurrences causally related to treatment / all	3 / 87		
deaths causally related to treatment / all	0 / 1		
Cardiomyopathy subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest subjects affected / exposed	7 / 4687 (0.15%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 6		
Cardiogenic shock subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Cardiopulmonary failure subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiovascular insufficiency subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiorenal syndrome subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiovascular disorder subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	50 / 4687 (1.07%)			
occurrences causally related to treatment / all	1 / 59			
deaths causally related to treatment / all	0 / 0			
Congestive cardiomyopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery occlusion				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Coronary artery insufficiency				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	1 / 11			
deaths causally related to treatment / all	0 / 0			
Cyanosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diastolic dysfunction				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive heart disease				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			

Hypertensive cardiomyopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracardiac thrombus				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic cardiomyopathy				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Left atrial dilatation				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Left ventricular dysfunction				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Left ventricular failure				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mitral valve incompetence				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Microvascular coronary artery disease				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				

subjects affected / exposed	12 / 4687 (0.26%)		
occurrences causally related to treatment / all	1 / 12		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	94 / 4687 (2.01%)		
occurrences causally related to treatment / all	9 / 103		
deaths causally related to treatment / all	0 / 21		
Myocarditis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nodal arrhythmia			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial cyst			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Papillary muscle disorder			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	2 / 4687 (0.04%)		

occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Postinfarction angina			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Right ventricular failure			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Silent myocardial infarction			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	3 / 6		
deaths causally related to treatment / all	0 / 0		
Sinus arrhythmia			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus bradycardia			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Sinus node dysfunction			
subjects affected / exposed	8 / 4687 (0.17%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Systolic dysfunction			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Tachycardia paroxysmal			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trifascicular block			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular fibrillation			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Ventricular arrhythmia			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	7 / 4687 (0.15%)		
occurrences causally related to treatment / all	1 / 7		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0		
Congenital anomalies of ear ossicles			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocele			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phimosis			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pyloric stenosis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	15 / 4687 (0.32%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic anaemia			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		

deaths causally related to treatment / all	0 / 0			
Hypereosinophilic syndrome				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypochromic anaemia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypocoagulable state				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Microcytic anaemia				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Normochromic normocytic anaemia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amnesia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Autonomic neuropathy			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Balance disorder			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain stem haemorrhage			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Brain stem infarction			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Brain stem stroke			

subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain stem ischaemia			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid arteriosclerosis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery disease			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carotid artery occlusion			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	19 / 4687 (0.41%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 0		
Carotid artery thrombosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Central nervous system inflammation			
subjects affected / exposed	1 / 4687 (0.02%)		

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar infarction			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral artery occlusion			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cerebral artery stenosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral ataxia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	18 / 4687 (0.38%)		
occurrences causally related to treatment / all	1 / 18		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	83 / 4687 (1.77%)		
occurrences causally related to treatment / all	0 / 86		
deaths causally related to treatment / all	0 / 5		
Cerebral ischaemia			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		

deaths causally related to treatment / all	0 / 0			
Cervical cord compression				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular insufficiency				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cervical myelopathy				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cervical radiculopathy				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Complex partial seizures				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coordination abnormal				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Dementia Alzheimer's type				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Diabetic neuropathy				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	13 / 4687 (0.28%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Dysarthria				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Embolic cerebral infarction				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Embolic stroke				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Generalised tonic-clonic seizure				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic stroke			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hemiplegia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Hypercapnic coma				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperkinesia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive encephalopathy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemic coma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypotonia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
IIIrd nerve paralysis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intercostal neuralgia				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Ischaemic cerebral infarction				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	38 / 4687 (0.81%)			
occurrences causally related to treatment / all	2 / 42			
deaths causally related to treatment / all	0 / 4			
Lacunar infarction				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Leukoencephalopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lumbar radiculopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolic encephalopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mononeuritis				
subjects affected / exposed	0 / 4687 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Monoplegia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle spasticity				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myelitis transverse				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Myelopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myoclonus				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Nerve root compression				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuroleptic malignant syndrome				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuropathy peripheral				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraplegia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraparesis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parkinson's disease				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial seizures				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral motor neuropathy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peroneal nerve palsy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Petit mal epilepsy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Piriformis syndrome				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Radiculopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	12 / 4687 (0.26%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Sensory disturbance				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal epidural haematoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	5 / 4687 (0.11%)			

occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Spondylitic myelopathy			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	27 / 4687 (0.58%)		
occurrences causally related to treatment / all	3 / 28		
deaths causally related to treatment / all	0 / 0		
Subdural hygroma			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thalamic infarction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombotic cerebral infarction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombotic stroke			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Transient ischaemic attack			
subjects affected / exposed	53 / 4687 (1.13%)		
occurrences causally related to treatment / all	0 / 54		
deaths causally related to treatment / all	0 / 0		
VIIth nerve paralysis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0		
Vascular encephalopathy			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebral artery dissection			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vertebral artery stenosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vocal cord paresis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Amaurosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blindness unilateral			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blindness			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Cataract cortical				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cataract				
subjects affected / exposed	24 / 4687 (0.51%)			
occurrences causally related to treatment / all	0 / 29			
deaths causally related to treatment / all	0 / 0			
Exfoliation syndrome				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic retinopathy				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Corneal degeneration				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Keratopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Glaucoma				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Macular fibrosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Macular oedema				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retinal artery occlusion				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Papilloedema				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal haemorrhage				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal tear				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retinal detachment				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Retinopathy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinoschisis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Visual acuity reduced				
subjects affected / exposed	0 / 4687 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous haemorrhage			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Vitreous opacities			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Deafness unilateral			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerumen impaction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tinnitus			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden hearing loss			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all			
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	11 / 4687 (0.23%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	7 / 4687 (0.15%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia obstructive			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	5 / 4687 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Anal fistula				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Chronic gastritis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bezoar				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon dysplasia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Crohn's disease				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Constipation				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Dental caries				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic gastroparesis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic gastropathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal perforation				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	2 / 4687 (0.04%)			

occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer haemorrhage				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer perforation				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dyspepsia				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epigastric discomfort				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Erosive duodenitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Food poisoning				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Faecaloma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric perforation				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric polyps				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer haemorrhage				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Gastritis				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer perforation				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastritis erosive				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastritis haemorrhagic				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroduodenal ulcer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroduodenitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal angiodysplasia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	8 / 4687 (0.17%)			

occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal inflammation				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Gingival bleeding				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Haemorrhoids thrombosed				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Impaired gastric emptying				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Incarcerated umbilical hernia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia strangulated				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intestinal haemorrhage				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Intestinal obstruction				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Intestinal perforation				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Irritable bowel syndrome				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestinal ulcer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Localised intraabdominal fluid collection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar hernia				

subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Melaena			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Oesophageal stenosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Pancreatitis chronic			
subjects affected / exposed	0 / 4687 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	2 / 4		
deaths causally related to treatment / all	0 / 0		
Pancreatitis relapsing			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peptic ulcer perforation			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritoneal haemorrhage			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Small intestinal obstruction			
subjects affected / exposed	5 / 4687 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		

deaths causally related to treatment / all	0 / 0			
Small intestinal perforation				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stress ulcer				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subileus				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombosis mesenteric vessel				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Volvulus				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Varices oesophageal			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	7 / 4687 (0.15%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Albuminuria			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute prerenal failure			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	45 / 4687 (0.96%)		
occurrences causally related to treatment / all	4 / 46		
deaths causally related to treatment / all	0 / 0		
Anuria			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder neck sclerosis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder outlet obstruction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus bladder			

subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus ureteric			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystitis glandularis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Cystitis haemorrhagic			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysuria			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic nephropathy			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	2 / 4687 (0.04%)		

occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Lower urinary tract symptoms				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertensive nephropathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Nephritis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Microalbuminuria				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Nephrotic syndrome				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephropathy				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 3			

deaths causally related to treatment / all	0 / 0			
Oliguria				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive uropathy				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Polyuria				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery arteriosclerosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery stenosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal colic				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cyst				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal impairment				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			

Renal failure				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	1 / 6			
deaths causally related to treatment / all	0 / 1			
Renal tubular necrosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress urinary incontinence				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal infarct				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ureteric obstruction				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tubulointerstitial nephritis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urethral stenosis				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Urinary bladder haemorrhage				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary incontinence				
subjects affected / exposed	0 / 4687 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary bladder polyp			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	9 / 4687 (0.19%)		
occurrences causally related to treatment / all	1 / 10		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cold sweat			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermal cyst			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis contact			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic bullosis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Diabetic foot				
subjects affected / exposed	21 / 4687 (0.45%)			
occurrences causally related to treatment / all	0 / 24			
deaths causally related to treatment / all	0 / 0			
Eczema				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erythema				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erythrodermic psoriasis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ingrowing nail				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leukoplakia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuropathic ulcer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pemphigus				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0		
Skin fibrosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin necrosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	17 / 4687 (0.36%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 1		
Skin ulcer haemorrhage			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	11 / 4687 (0.23%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		

deaths causally related to treatment / all	0 / 0			
Bone fistula				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Costochondritis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cervical spinal stenosis				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Dactylitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dupuytren's contracture				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fistula				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Flank pain				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Fracture delayed union				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fracture nonunion				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gouty arthritis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gouty tophus				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc compression				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc degeneration				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	10 / 4687 (0.21%)			

occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Lower extremity mass				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Muscle tightness				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle twitching				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal disorder				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Myofascial pain syndrome				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Neuropathic arthropathy				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Osteitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteitis deformans				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	32 / 4687 (0.68%)			
occurrences causally related to treatment / all	0 / 34			
deaths causally related to treatment / all	0 / 0			

Osteomalacia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoporosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteoporotic fracture				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Periarthritis				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	1 / 6			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	7 / 4687 (0.15%)			

occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Spinal column stenosis				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Spinal pain				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spondylitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spondylolisthesis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Synovitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendonitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tenosynovitis stenosans				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0		
Trigger finger			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism primary			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	10 / 4687 (0.21%)		
occurrences causally related to treatment / all	2 / 11		

deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Diabetes mellitus inadequate control				
subjects affected / exposed	11 / 4687 (0.23%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Diabetic complication				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diabetic metabolic decompensation				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fluid overload				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gout				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	8 / 4687 (0.17%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			

Hyperkalaemia				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypervolaemia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Hypoglycaemia				
subjects affected / exposed	19 / 4687 (0.41%)			
occurrences causally related to treatment / all	6 / 20			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypomagnesaemia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Insulin resistance				
subjects affected / exposed	0 / 4687 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lactic acidosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lipomatosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal wall abscess			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abscess			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to	0 / 1		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	8 / 4687 (0.17%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Abscess of eyelid				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute sinusitis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Amoebiasis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Amoebic dysentery				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	8 / 4687 (0.17%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Appendicitis perforated				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			

deaths causally related to treatment / all	0 / 0			
Arteriosclerotic gangrene				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthritis bacterial				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Biliary tract infection				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone abscess				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Bronchitis				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Bronchitis viral				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	28 / 4687 (0.60%)			
occurrences causally related to treatment / all	0 / 37			
deaths causally related to treatment / all	0 / 0			
Catheter site infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis gangrenous				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cellulitis staphylococcal				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis of male external genital organ				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				

subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic sinusitis			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystitis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cutaneous larva migrans			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis bacterial			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diabetic foot infection			
subjects affected / exposed	12 / 4687 (0.26%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	0 / 4687 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related sepsis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic gangrene			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ear infection			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eczema infected			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Empyema			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endophthalmitis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Enterocolitis infectious				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis viral				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	13 / 4687 (0.28%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Epididymitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Furuncle				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Gallbladder empyema				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	16 / 4687 (0.34%)			
occurrences causally related to treatment / all	0 / 19			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	33 / 4687 (0.70%)			
occurrences causally related to treatment / all	3 / 35			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal protozoal infection				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Giardiasis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
H1N1 influenza				
subjects affected / exposed	3 / 4687 (0.06%)			

occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Incision site infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Infectious colitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infectious pleural effusion				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia gangrenous				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infusion site infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal fistula infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Intestinal tuberculosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Labyrinthitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Kidney infection				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lobar pneumonia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Liver abscess				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			

Lung infection				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lyme disease				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection bacterial				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mediastinitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis streptococcal				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis bacterial				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscle abscess				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis tuberculous				

subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelitis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasal abscess			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal candidiasis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	14 / 4687 (0.30%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis acute			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis bacterial			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis chronic			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	0 / 4687 (0.00%)		

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Peritonsillar abscess				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Periodontitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pertussis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	79 / 4687 (1.69%)			
occurrences causally related to treatment / all	0 / 86			

deaths causally related to treatment / all	0 / 6			
Pneumonia influenzal				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia haemophilus				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia pneumococcal				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural sepsis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Postoperative wound infection				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Prostatic abscess				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Pseudomonal sepsis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psoas abscess				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary mycosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	2 / 5			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis chronic				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhinitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Salmonellosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal abscess				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	13 / 4687 (0.28%)			
occurrences causally related to treatment / all	1 / 13			
deaths causally related to treatment / all	0 / 4			
Septic encephalopathy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	1 / 7			
deaths causally related to treatment / all	1 / 3			
Sinusitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal skin infection				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tuberculosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tuberculous pleurisy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Upper respiratory tract infection subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection subjects affected / exposed	29 / 4687 (0.62%)			
occurrences causally related to treatment / all	9 / 30			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection fungal subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection pseudomonal subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urosepsis subjects affected / exposed	17 / 4687 (0.36%)			
occurrences causally related to treatment / all	6 / 18			
deaths causally related to treatment / all	2 / 2			
Vaginal cellulitis subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Varicella subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vestibular neuronitis subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral infection subjects affected / exposed	7 / 4687 (0.15%)			

occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	7 / 4687 (0.15%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Wound sepsis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aneurysm			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angiopathy			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			
subjects affected / exposed	7 / 4687 (0.15%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Aortic arteriosclerosis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Aortic stenosis				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 1			
Arterial disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arterial haemorrhage				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arterial occlusive disease				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arterial stenosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Arteriovenous fistula				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteritis				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			

deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	13 / 4687 (0.28%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Diabetic microangiopathy				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Embolism arterial				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Extremity necrosis				
subjects affected / exposed	12 / 4687 (0.26%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Femoral artery embolism				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femoral artery occlusion				
subjects affected / exposed	8 / 4687 (0.17%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			

Haemorrhage				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	11 / 4687 (0.23%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Hypertensive emergency				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Iliac artery occlusion				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Infarction				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intermittent claudication				
subjects affected / exposed	9 / 4687 (0.19%)			

occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Ischaemia				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Leriche syndrome				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant hypertension				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	58 / 4687 (1.24%)			
occurrences causally related to treatment / all	1 / 75			
deaths causally related to treatment / all	0 / 0			
Peripheral artery aneurysm				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	12 / 4687 (0.26%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Peripheral coldness				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral embolism				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	15 / 4687 (0.32%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Peripheral vascular disorder				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	1 / 11			
deaths causally related to treatment / all	0 / 0			
Peripheral venous disease				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subclavian artery stenosis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis superficial				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Thrombosis			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Varicose ulceration			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular calcification			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular insufficiency			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Venous occlusion			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis limb			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			

Angioplasty				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Coronary angioplasty				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Coronary arterial stent insertion				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Coronary artery bypass				
subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Coronary revascularisation				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Fracture treatment				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Percutaneous coronary intervention				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Prophylaxis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stent placement				
subjects affected / exposed	3 / 4687 (0.06%)			

occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Acute lymphocytic leukaemia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Acute myeloid leukaemia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma gastric			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma pancreas			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 4		
Adenoma benign			
subjects affected / exposed	1 / 4687 (0.02%)		

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anogenital warts			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	27 / 4687 (0.58%)		
occurrences causally related to treatment / all	0 / 29		
deaths causally related to treatment / all	0 / 0		
Basosquamous carcinoma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign hepatic neoplasm			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign laryngeal neoplasm			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign lung neoplasm			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign neoplasm of adrenal gland			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Benign neoplasm of bladder subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of prostate subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of thyroid gland subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign pancreatic neoplasm subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign respiratory tract neoplasm subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Benign uterine neoplasm subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bile duct cancer subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder cancer subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	1 / 6			
deaths causally related to treatment / all	0 / 2			

Bladder cancer recurrent subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Bone cancer subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bone giant cell tumour benign subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bowen's disease subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Breast cancer subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac myxoma subjects affected / exposed	0 / 4687 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervix carcinoma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholesteatoma			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic lymphocytic leukaemia			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Clear cell renal cell carcinoma			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Colon adenoma			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colon cancer			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 2		
Colon cancer metastatic			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 3		
Colon neoplasm			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Colorectal adenocarcinoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colorectal cancer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endometrial cancer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Fibroadenoma of breast				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibrosarcoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Follicular thyroid cancer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal stromal tumour				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Genital neoplasm malignant female subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemangioma of bone subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemangioma of liver subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic neoplasm subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatocellular carcinoma subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 2			
Hodgkin's disease stage I subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraductal proliferative breast lesion subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Keratoacanthoma subjects affected / exposed	3 / 4687 (0.06%)			

occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Large cell lung cancer				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal cancer				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Laryngeal squamous cell carcinoma				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Lipoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	8 / 4687 (0.17%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 3			
Lung cancer metastatic				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lung carcinoma cell type unspecified stage III				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	8 / 4687 (0.17%)			
occurrences causally related to treatment / all	0 / 9			

deaths causally related to treatment / all	0 / 4			
Lung squamous cell carcinoma stage III				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphocytic lymphoma				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphoproliferative disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of unknown primary site				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningioma				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			

deaths causally related to treatment / all	0 / 0			
Malignant neoplasm progression subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to bone subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Metastases to liver subjects affected / exposed	10 / 4687 (0.21%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 4			
Metastases to lung subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Metastases to lymph nodes subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to peritoneum subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Metastases to neck subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to pleura subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Metastasis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Metastatic malignant melanoma				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelodysplastic syndrome				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic renal cell carcinoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasopharyngeal cancer				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Non-Hodgkin's lymphoma stage IV				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma of the skin				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma				

subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal adenocarcinoma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oesophageal carcinoma			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
POEMS syndrome			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	1 / 3		
Papillary serous endometrial carcinoma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parathyroid tumour benign			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour benign			
subjects affected / exposed	1 / 4687 (0.02%)		

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Penile squamous cell carcinoma subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Plasma cell myeloma subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Prostate cancer subjects affected / exposed	20 / 4687 (0.43%)			
occurrences causally related to treatment / all	0 / 20			
deaths causally related to treatment / all	0 / 0			
Rectal adenocarcinoma subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 2			
Prostate cancer recurrent subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatic adenoma subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rectal cancer subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Renal cancer subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Renal cancer metastatic				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma stage I				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma stage II				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salivary gland neoplasm				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Salivary gland adenoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin cancer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small cell carcinoma				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Sarcoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Splenic marginal zone lymphoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Small cell lung cancer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 3			
Squamous cell carcinoma of skin				
subjects affected / exposed	7 / 4687 (0.15%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Transitional cell carcinoma				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Thyroid neoplasm				

subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine cancer			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tumour haemorrhage			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Anaphylactic shock			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Contrast media allergy			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food allergy			

subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iodine allergy			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Physical assault			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac death			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 6		
Asthenia			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chest discomfort			
subjects affected / exposed	5 / 4687 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		

Chest pain				
subjects affected / exposed	65 / 4687 (1.39%)			
occurrences causally related to treatment / all	1 / 68			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	15 / 4687 (0.32%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 15			
Device defective				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device deposit issue				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device difficult to use				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device malfunction				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device occlusion				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Drug ineffective				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Drowning				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Dysplasia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Extravasation				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gait disturbance				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Feeling abnormal				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Granuloma				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hernia				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired healing				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Implant site necrosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multi-organ failure				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Necrobiosis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	20 / 4687 (0.43%)			
occurrences causally related to treatment / all	1 / 20			
deaths causally related to treatment / all	0 / 0			

Oedema peripheral				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oversensing				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pacemaker generated arrhythmia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perforated ulcer				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Polyp				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral swelling				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Strangulated hernia				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stent malfunction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	13 / 4687 (0.28%)		
occurrences causally related to treatment / all	1 / 13		
deaths causally related to treatment / all	1 / 13		
Sudden cardiac death			
subjects affected / exposed	4 / 4687 (0.09%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 4		
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ulcer			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Anxiety			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	3 / 4687 (0.06%)		

occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Hallucination				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Insomnia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Major depression				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rapid eye movements sleep abnormal				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Substance abuse				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	18 / 4687 (0.38%)		
occurrences causally related to treatment / all	1 / 19		
deaths causally related to treatment / all	0 / 1		
Endometrial hyperplasia			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystocele			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fibrocystic breast disease			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Genital prolapse			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Menorrhagia			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Gynaecomastia				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatic obstruction				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostatism				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Uterine polyp				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatitis				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	2 / 4			
deaths causally related to treatment / all	0 / 0			
Uterovaginal prolapse				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine prolapse				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Vaginal prolapse			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	8 / 4687 (0.17%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 2		
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	8 / 4687 (0.17%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 2		
Allergic sinusitis			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Atelectasis			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchial disorder			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Bronchial secretion retention				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchiectasis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis chronic				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	16 / 4687 (0.34%)			
occurrences causally related to treatment / all	0 / 21			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	15 / 4687 (0.32%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Dyspnoea exertional				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Emphysema				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epistaxis				

subjects affected / exposed	5 / 4687 (0.11%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemothorax			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrothorax			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	3 / 4687 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 4687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Interstitial lung disease			
subjects affected / exposed	2 / 4687 (0.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Laryngeal oedema			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	1 / 4687 (0.02%)		

occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mediastinal haematoma				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasal polyps				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paranasal cyst				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	5 / 4687 (0.11%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Pleural fibrosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pleurisy				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Pleuritic pain				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pulmonary arterial hypertension				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 1			
Pulmonary fibrosis				
subjects affected / exposed	2 / 4687 (0.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			

Pulmonary hypertension				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pulmonary mass				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	3 / 4687 (0.06%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pulmonary thrombosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary toxicity				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory arrest				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	6 / 4687 (0.13%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Sinus disorder				
subjects affected / exposed	1 / 4687 (0.02%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Status asthmaticus			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper airway obstruction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord polyp			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vocal cord thickening			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	1 / 4687 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			
subjects affected / exposed	6 / 4687 (0.13%)		
occurrences causally related to treatment / all	1 / 6		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	13 / 4687 (0.28%)		
occurrences causally related to	0 / 13		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	9 / 4687 (0.19%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis chronic				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	21 / 4687 (0.45%)			
occurrences causally related to treatment / all	1 / 21			
deaths causally related to treatment / all	0 / 0			
Gallbladder disorder				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholestasis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic cirrhosis				
subjects affected / exposed	4 / 4687 (0.09%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Ischaemic hepatitis				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic function abnormal				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic steatosis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Jaundice cholestatic				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Non-alcoholic steatohepatitis				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post cholecystectomy syndrome				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Portal hypertension				
subjects affected / exposed	1 / 4687 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sphincter of Oddi dysfunction				
subjects affected / exposed	0 / 4687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Placebo	Empagliflozin 10 mg	Empagliflozin 25 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1690 / 2333 (72.44%)	1556 / 2345 (66.35%)	1551 / 2342 (66.23%)
Vascular disorders			
Hypertension			
subjects affected / exposed	210 / 2333 (9.00%)	154 / 2345 (6.57%)	176 / 2342 (7.51%)
occurrences (all)	251	176	209
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	146 / 2333 (6.26%)	119 / 2345 (5.07%)	108 / 2342 (4.61%)
occurrences (all)	177	133	124
Nervous system disorders			
Dizziness			
subjects affected / exposed	151 / 2333 (6.47%)	170 / 2345 (7.25%)	173 / 2342 (7.39%)
occurrences (all)	198	215	245
Headache			
subjects affected / exposed	123 / 2333 (5.27%)	100 / 2345 (4.26%)	124 / 2342 (5.29%)
occurrences (all)	158	146	166
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	155 / 2333 (6.64%)	84 / 2345 (3.58%)	75 / 2342 (3.20%)
occurrences (all)	171	96	83
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	109 / 2333 (4.67%)	91 / 2345 (3.88%)	119 / 2342 (5.08%)
occurrences (all)	117	99	130
Diarrhoea			
subjects affected / exposed	171 / 2333 (7.33%)	145 / 2345 (6.18%)	144 / 2342 (6.15%)
occurrences (all)	217	184	169
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	130 / 2333 (5.57%)	107 / 2345 (4.56%)	148 / 2342 (6.32%)
occurrences (all)	142	119	169
Pain in extremity			
subjects affected / exposed	133 / 2333 (5.70%)	114 / 2345 (4.86%)	101 / 2342 (4.31%)
occurrences (all)	147	128	113
Back pain			
subjects affected / exposed	148 / 2333 (6.34%)	149 / 2345 (6.35%)	166 / 2342 (7.09%)
occurrences (all)	181	168	178
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	685 / 2333 (29.36%)	694 / 2345 (29.59%)	673 / 2342 (28.74%)
occurrences (all)	5225	4199	4246
Hyperglycaemia			
subjects affected / exposed	423 / 2333 (18.13%)	217 / 2345 (9.25%)	202 / 2342 (8.63%)
occurrences (all)	1188	442	405
Infections and infestations			
Influenza			
subjects affected / exposed	165 / 2333 (7.07%)	134 / 2345 (5.71%)	149 / 2342 (6.36%)
occurrences (all)	237	181	191
Bronchitis			
subjects affected / exposed	164 / 2333 (7.03%)	129 / 2345 (5.50%)	117 / 2342 (5.00%)
occurrences (all)	223	157	150
Nasopharyngitis			
subjects affected / exposed	217 / 2333 (9.30%)	210 / 2345 (8.96%)	220 / 2342 (9.39%)
occurrences (all)	301	291	289
Upper respiratory tract infection			
subjects affected / exposed	199 / 2333 (8.53%)	191 / 2345 (8.14%)	175 / 2342 (7.47%)
occurrences (all)	266	266	266
Urinary tract infection			
subjects affected / exposed	344 / 2333 (14.74%)	339 / 2345 (14.46%)	337 / 2342 (14.39%)
occurrences (all)	538	598	578

Non-serious adverse events	All Empagliflozin		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3107 / 4687 (66.29%)		

Vascular disorders Hypertension subjects affected / exposed occurrences (all)	330 / 4687 (7.04%) 385		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	227 / 4687 (4.84%) 257		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all)	343 / 4687 (7.32%) 460 224 / 4687 (4.78%) 312		
General disorders and administration site conditions Oedema peripheral subjects affected / exposed occurrences (all)	159 / 4687 (3.39%) 179		
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	210 / 4687 (4.48%) 229 289 / 4687 (6.17%) 353		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all)	255 / 4687 (5.44%) 288 215 / 4687 (4.59%) 241 315 / 4687 (6.72%) 346		

Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1367 / 4687 (29.17%)		
occurrences (all)	8445		
Hyperglycaemia			
subjects affected / exposed	419 / 4687 (8.94%)		
occurrences (all)	847		
Infections and infestations			
Influenza			
subjects affected / exposed	283 / 4687 (6.04%)		
occurrences (all)	372		
Bronchitis			
subjects affected / exposed	246 / 4687 (5.25%)		
occurrences (all)	307		
Nasopharyngitis			
subjects affected / exposed	430 / 4687 (9.17%)		
occurrences (all)	580		
Upper respiratory tract infection			
subjects affected / exposed	366 / 4687 (7.81%)		
occurrences (all)	532		
Urinary tract infection			
subjects affected / exposed	676 / 4687 (14.42%)		
occurrences (all)	1176		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 September 2010	<p>With the introduction of this amendment, cardiovascular outcome events were exempt from the expedited unblinded reporting process if they occurred during the randomised treatment period to preclude reporting of unblinded outcome events while this double-blind study was ongoing. Cardiovascular outcome events were to be reported in specific eCRF pages instead of on paper SAE forms since the reporting of outcome events by treatment group during the trial (by anyone except the DMC) could potentially jeopardise the integrity of the trial. Cardiovascular outcome events that occurred during the screening/run in phase were to be considered as SAEs and not as outcome events. Additionally, hepatic injury was added a significant AE to comply with FDA guidelines for DILI.</p>
22 April 2011	<p>Inclusion criterion:Maximum HbA1c for treatment naïve patients was raised to 9.0% from 8.0% and definition of patients with high CV risk was expanded to include single vessel disease,and further clarification of criteria to be met for inclusion of patients with peripheral artery disease,unstable angina,multivessel disease was provided.</p> <p>Exclusion criteria:Acute coronary syndrome, stroke or TIA within 2 months prior to informed consent was added; sibutramine and orlistat were removed as specifically named anti-obesity drugs.</p> <p>Duration of follow-up after regular completion of treatment period was increased from 1 to 4 weeks.</p> <p>Endpoints:Primary endpoint wording was clarified to indicate when patients without events would be censored,Weight and waist circumference measurements at Week 12 were added as further endpoints, Heart failure requiring hospitalization moved from tertiary CV endpoints to secondary endpoints; composite microvascular outcome added as secondary endpoint; Hospitalisation for unstable angina and components of microvascular composite endpoint added as tertiary endpoints.With regard to hypoglycaemic events to be documented in the eCRF,every episode of plasma glucose below 70 was corrected to ≤ 70 mg/dL (3.9 mmol/L).</p> <p>Clarification of safety laboratory assessments procedures.</p> <p>Statistical analyses:Age & gender were added as covariates to primary analysis model; clarification of non-inferiority margin and order of testing for primary, secondary endpoints both for non-inferiority and then superiority;a 4-step hierarchical testing strategy to include key secondary endpoint was specified.</p> <p>Trial design description was clarified to indicate that randomisation would be stopped after 4000 patients had been randomised.</p> <p>Clarified that while there was no interim analysis planned on the trial level, there was a pre-specified meta-analysis to assess the cardiovascular safety profile of empagliflozin, which included data from this trial.</p>

29 December 2011	<p>The non-inferiority margin of 1.8 and the 2 corresponding tests (of the primary and key secondary endpoint), defined as steps 1 and 2 in the hierarchical testing strategy were removed. Hence the test for non-inferiority of the primary endpoint using the non-inferiority margin of 1.3 was defined to be the first test, followed by testing non inferiority of key secondary endpoint etc. Number of patients with primary endpoint events required was changed from 137 to 691 to ensure a power of 90% for testing non-inferiority based on margin of 1.3, using an overall one-sided alpha of 0.025 and 0.0249 for the final analysis.</p> <p>Total number of planned randomised patients was increased from 4000 to 7000 . Planned treatment duration of the patients was changed from an anticipated 206 weeks to approximately 300 to 420 weeks.</p> <p>An interim analysis of this trial to support a New Drug Application (NDA) was part of the cardiovascular meta-analysis using the interim data of this trial. It was projected that approximately 80 confirmed primary events would have been observed from this trial at that time. The interim analysis and the cardiovascular meta-analysis were to be performed by a team independent from the 1245.25 trial team so that the trial team remained blinded to the results.</p> <p>A Haybittle-Peto boundary was used to maintain the experiment-wise overall α level of 0.025.</p> <p>Clarification, that primary & key secondary endpoints did not include silent MI. Further secondary endpoints were revised to new onset albuminuria defined as UACR ≥ 30 mg/g and new onset macroalbuminuria ≥ 300 mg/g.</p> <p>Death due to renal disease was added to definition of new or worsening nephropathy.</p> <p>Weight & waist circumference were to be measured annually.</p> <p>hs CR, hs Troponin T, cystatin C, indicators of cardiac risk were to be measured.</p> <p>Procedures for clinical evaluation of liver injury were added.</p> <p>An additional sample for assessment of PK in AESIs was to be collected.</p>
15 October 2013	<p>Main changes:</p> <ul style="list-style-type: none"> - Clarification that the follow-up period of 4 weeks means 30 days - Procedures to be performed for patients on study medication at the time of study completion were clarified - It was clarified that a minimum of 691 events for the planned primary analysis referred to 3-point MACE - The central adjudication of malignancies and hepatic events was added

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

2 sets of duplicates (4 patients (pts)) were counted only once. 652 sites were initiated and 611 enrolled. One site transferred all pts to other sites. 27 pts randomised and 13 pts screened were excluded from analyses due to serious non-compliance

Notes: