



Clinical trial results:

The efficacy and safety of Trimetazidine in Patients with angina pectoris having been treated by percutaneous Coronary Intervention.

ATPCI study. An international, multicentre, randomised, double-blind, placebo-controlled study in patients treated for 2 to 4 years.

Summary

EudraCT number	2010-022134-89
Trial protocol	HU IT LV ES NL EE SK CZ LT SI GR DK PL AT HR PT
Global end of trial date	13 December 2019

Results information

Result version number	v1 (current)
This version publication date	19 December 2020
First version publication date	19 December 2020

Trial information

Trial identification

Sponsor protocol code	CL3-06790-010
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	U1111-1145-1743

Notes:

Sponsors

Sponsor organisation name	Institut de Recherches Internationales Servier
Sponsor organisation address	50 rue Carnot, Suresnes, France, 92284
Public contact	Cardiovascular and Metabolism Centre of Therapeutic Innovation, Institut de Recherches Internationales Servier, +33 01.55.72.43.66, clinicaltrials@servier.com
Scientific contact	Cardiovascular and Metabolism Centre of Therapeutic Innovation, Institut de Recherches Internationales Servier, +33 01.55.72.43.66, clinicaltrials@servier.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 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 December 2019
Global end of trial reached?	Yes
Global end of trial date	13 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Demonstrate the superiority of trimetazidine over placebo in preventing recurrence or exacerbation of angina pectoris, in reducing cardiac events, and to document its safety by analysing the occurrence of serious adverse events (SAEs).

Protection of trial subjects:

This study was conducted in accordance with Good Clinical Practice standards, ethical principles stated in the Declaration of Helsinki and applicable regulatory requirements. After the subject has ended his/her participation in the trial, the investigator provided appropriate medication and/or arranged access to appropriate care for the patient.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 September 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Slovakia: 150
Country: Number of subjects enrolled	Spain: 275
Country: Number of subjects enrolled	Turkey: 110
Country: Number of subjects enrolled	Ukraine: 454
Country: Number of subjects enrolled	Vietnam: 69
Country: Number of subjects enrolled	Algeria: 60
Country: Number of subjects enrolled	Argentina: 244
Country: Number of subjects enrolled	Austria: 28
Country: Number of subjects enrolled	Belarus: 114
Country: Number of subjects enrolled	Bosnia and Herzegovina: 120
Country: Number of subjects enrolled	Brazil: 280
Country: Number of subjects enrolled	China: 199
Country: Number of subjects enrolled	Colombia: 105
Country: Number of subjects enrolled	Croatia: 230
Country: Number of subjects enrolled	Czech Republic: 295
Country: Number of subjects enrolled	France: 60
Country: Number of subjects enrolled	Georgia: 300
Country: Number of subjects enrolled	Greece: 40
Country: Number of subjects enrolled	Italy: 260

Country: Number of subjects enrolled	Korea, Republic of: 203
Country: Number of subjects enrolled	Montenegro: 74
Country: Number of subjects enrolled	Peru: 110
Country: Number of subjects enrolled	Poland: 771
Country: Number of subjects enrolled	Portugal: 80
Country: Number of subjects enrolled	Romania: 297
Country: Number of subjects enrolled	Russian Federation: 809
Country: Number of subjects enrolled	Serbia: 322
Worldwide total number of subjects	6059
EEA total number of subjects	2486

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)	3868
From 65 to 84 years	2191
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Male or female patients, aged from 21 to 85 years old (exclusive) patients with single or multi-vessel CAD having undergone a recent successful PCI (maximum 30 days before randomisation).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Trimetazidine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Trimetazidine MR 35 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Trimetazidine MR 35 mg b.i.d.: one tablet in the morning and in the evening, at mealtimes (o.d. in case of moderate renal failure).

Arm title	Placebo
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Arm description: -

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

Dosage and administration details:

Placebo b.i.d.: one tablet in the morning and the evening, at mealtimes (o.d. in case of moderate renal failure).

Number of subjects in period 1^[1]	Trimetazidine	Placebo
Started	2998	3009
Completed	2729	2725
Not completed	269	284
Consent withdrawn by subject	115	117

Death	141	151
Lost to follow-up	-	2
Other non medical reason	13	14

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 have been done in the Efficacy Analysis Set (All patients of the Randomised Set, except 52 patients with a possible unblinding due to a technical error at the beginning of the study).

Baseline characteristics

Reporting groups

Reporting group title	Trimetazidine
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Trimetazidine	Placebo	Total
Number of subjects	2998	3009	6007
Age categorical Units: Subjects			
Adults (18-64 years)	1900	1930	3830
From 65-84 years	1098	1079	2177
Age continuous Units: years			
arithmetic mean	61.1	60.7	
standard deviation	± 9.6	± 9.8	-
Gender categorical Units: Subjects			
Female	687	696	1383
Male	2311	2313	4624

Subject analysis sets

Subject analysis set title	Efficacy analysis set
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All included patients with a randomization number allocated, except 52 patients with a potential unblinding due to a technical error at the beginning of the study.

Reporting group values	Efficacy analysis set		
Number of subjects	6007		
Age categorical Units: Subjects			
Adults (18-64 years)	3830		
From 65-84 years	2177		
Age continuous Units: years			
arithmetic mean	60.9		
standard deviation	± 9.7		
Gender categorical Units: Subjects			
Female	1383		
Male	4624		

End points

End points reporting groups

Reporting group title	Trimetazidine
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Subject analysis set title	Efficacy analysis set
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
All included patients with a randomization number allocated, except 52 patients with a potential unblinding due to a technical error at the beginning of the study.	

Primary: Primary Efficacy Composite Endpoint

End point title	Primary Efficacy Composite Endpoint
End point description:	
The Primary Composite Endpoint (PCE) was defined as the time to first event among:	
- Cardiac death (cardiac death and death from unknown cause).	
- Hospitalisation for a cardiac event (hospitalisation for acute MI, unstable angina, heart failure, sustained ventricular tachycardia, resuscitated cardiac arrest or angina and/or ischaemia leading to revascularisation).	
- Recurrent or persistent angina leading to adding, switching or increasing the dose of one of the evidence-based antianginal therapies (angina alone or with documented ischaemia).	
- Recurrent or persistent angina leading to performing a coronary angiography (angina alone or with documented ischaemia).	
End point type	Primary
End point timeframe:	
The PCE had to be positively adjudicated and occur during the efficacy time-window, i.e. between the randomisation date and the end of study date of the patient (or end of theoretical termination period).	

End point values	Trimetazidine	Placebo	Efficacy analysis set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2998	3009	6007	
Units: number of patients with at least 1 event	700	714	1414	

Statistical analyses

Statistical analysis title	Primary efficacy endpoint
Statistical analysis description:	
The method used is a Cox proportional hazards model adjusted on country and nature of index PCI.	
Comparison groups	Trimetazidine v Placebo

Number of subjects included in analysis	6007
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.727
Method	Cox proportional hazards model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.09

Primary: Primary Safety Endpoint

End point title	Primary Safety Endpoint
End point description:	
The main expression is Annual incidence of first Serious Treatment Emergent Adverse Events according to the investigator or sponsor opinion occurring during the treatment period.	
End point type	Primary
End point timeframe:	
During the treatment period : between the first IMP intake date (included) and the last IMP intake date + 2 days (included).	

End point values	Trimetazidine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2983	2944		
Units: number of patients with at least 1 event	1219	1230		

Statistical analyses

Statistical analysis title	Primary safety endpoint
Comparison groups	Trimetazidine v Placebo
Number of subjects included in analysis	5927
Analysis specification	Pre-specified
Analysis type	other ^[1]
Parameter estimate	Absolute difference in annual incidences
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.99
upper limit	0.81

Notes:

[1] - The confidence interval is provided for descriptive purpose.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All patients having taken at least one dose of Investigational Medicinal Product, except patients with a potential unblinding due to a technical error at the beginning of the study.

Adverse event reporting additional description:

Moreover, the patient having received the study treatment without randomisation, was counted in the treatment group corresponding to the therapeutic unit received at inclusion.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	21

Reporting groups

Reporting group title	Trimetazidine
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Trimetazidine	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1219 / 2983 (40.86%)	1230 / 2990 (41.14%)	
number of deaths (all causes)	108	120	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic neuroma			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	4 / 2983 (0.13%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	

Adenocarcinoma of colon		
subjects affected / exposed	4 / 2983 (0.13%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Adenocarcinoma pancreas		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Adrenal adenoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal squamous cell carcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiosarcoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Basal cell carcinoma		
subjects affected / exposed	7 / 2983 (0.23%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma of skin		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign bone neoplasm		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign pancreatic neoplasm		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct adenocarcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	3 / 2983 (0.10%)	11 / 2990 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage II		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage III		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Breast cancer		
subjects affected / exposed	1 / 2983 (0.03%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer male		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage I		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage III		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac myxoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Castleman's disease		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	4 / 2983 (0.13%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		

subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Colon cancer stage I		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Essential thrombocythaemia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ganglioglioma		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric adenoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric cancer stage I		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal cancer metastatic		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Glioblastoma multiforme		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemangioma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer metastatic		

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatocellular carcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Invasive breast carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine benign neoplasm		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer metastatic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyosarcoma		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip squamous cell carcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Lung adenocarcinoma recurrent		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung adenocarcinoma stage IV		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Lung carcinoma cell type unspecified stage II		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm malignant		

subjects affected / exposed	8 / 2983 (0.27%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 3
Lymphoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant melanoma		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Malignant neoplasm progression		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Meningioma		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Metastases to liver		

subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to pleura		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic neoplasm		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Monoclonal gammopathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myeloproliferative neoplasm		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neoplasm skin		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurilemmoma benign		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer metastatic		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal carcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 4
Pancreatic carcinoma metastatic		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic carcinoma stage IV		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic neoplasm		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Papillary renal cell carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraneoplastic syndrome		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural mesothelioma malignant		

subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Polycythaemia vera		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Primary myelofibrosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	9 / 2983 (0.30%)	12 / 2990 (0.40%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Prostate cancer stage I		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage II		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyogenic granuloma		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	5 / 2983 (0.17%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Rectosigmoid cancer metastatic		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cancer		
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma stage III		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Small cell lung cancer metastatic		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Small intestine carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Soft tissue neoplasm		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord neoplasm		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic marginal zone lymphoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma of skin		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Testis cancer		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid adenoma		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour necrosis		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine cancer			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	3 / 2983 (0.10%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic arteriosclerosis			
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic occlusion			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriosclerosis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriovenous fistula			

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure inadequately controlled		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brachiocephalic arteriosclerosis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Brachiocephalic artery stenosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Deep vein thrombosis		
subjects affected / exposed	9 / 2983 (0.30%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	4 / 2983 (0.13%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Granulomatosis with polyangiitis		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemodynamic instability		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	65 / 2983 (2.18%)	62 / 2990 (2.07%)
occurrences causally related to treatment / all	0 / 71	0 / 67
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	25 / 2983 (0.84%)	25 / 2990 (0.84%)
occurrences causally related to treatment / all	0 / 29	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	12 / 2983 (0.40%)	17 / 2990 (0.57%)
occurrences causally related to treatment / all	2 / 13	2 / 19
deaths causally related to treatment / all	0 / 0	0 / 1
Hypovolaemic shock		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		

subjects affected / exposed	3 / 2983 (0.10%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 3	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pallor		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	22 / 2983 (0.74%)	14 / 2990 (0.47%)
occurrences causally related to treatment / all	0 / 26	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	3 / 2983 (0.10%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Raynaud's phenomenon		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vasculitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Coronary arterial stent insertion			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 2983 (0.20%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	11 / 2983 (0.37%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 11	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	5 / 2983 (0.17%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 5	0 / 4	
Fatigue			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Foaming at mouth			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	10 / 2983 (0.34%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	5 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hyperthermia			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Non-cardiac chest pain			
subjects affected / exposed	14 / 2983 (0.47%)	14 / 2990 (0.47%)	
occurrences causally related to treatment / all	0 / 14	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			

subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden cardiac death			
subjects affected / exposed	8 / 2983 (0.27%)	5 / 2990 (0.17%)	
occurrences causally related to treatment / all	1 / 8	0 / 5	
deaths causally related to treatment / all	1 / 8	0 / 5	
Sudden death			
subjects affected / exposed	7 / 2983 (0.23%)	17 / 2990 (0.57%)	
occurrences causally related to treatment / all	0 / 7	0 / 17	
deaths causally related to treatment / all	0 / 7	0 / 17	
Temperature intolerance			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	3 / 2983 (0.10%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Contrast media allergy			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 2	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Impaired driving ability			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Victim of homicide			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired phimosis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenomyosis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	9 / 2983 (0.30%)	6 / 2990 (0.20%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical polyp			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial hyperplasia			
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymal cyst			

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Menorrhagia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian rupture		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic dysplasia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatism		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	4 / 2983 (0.13%)	5 / 2990 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Acute respiratory failure			
subjects affected / exposed	9 / 2983 (0.30%)	6 / 2990 (0.20%)	
occurrences causally related to treatment / all	0 / 9	0 / 6	
deaths causally related to treatment / all	0 / 2	0 / 1	
Apnoea			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			

subjects affected / exposed	16 / 2983 (0.54%)	9 / 2990 (0.30%)
occurrences causally related to treatment / all	0 / 24	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	4 / 2983 (0.13%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	10 / 2983 (0.34%)	10 / 2990 (0.33%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 0
Cough		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphonia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		

subjects affected / exposed	9 / 2983 (0.30%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	1 / 10	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea at rest		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	4 / 2983 (0.13%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	3 / 2983 (0.10%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Interstitial lung disease		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal polyp		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infiltration		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal mass		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polyps		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal pain		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paranasal cyst		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paranasal sinus mucosal hypertrophy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cyst		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural calcification		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	8 / 2983 (0.27%)	8 / 2990 (0.27%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 2
Pulmonary fibrosis		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	7 / 2983 (0.23%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary infarction		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	1 / 2983 (0.03%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory acidosis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		

subjects affected / exposed	2 / 2983 (0.07%)	5 / 2990 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Rhinitis allergic			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Adjustment disorder with anxiety			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	4 / 2983 (0.13%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	1 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Apathy		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 3
Confusional state		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Delusion		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed mood		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	23 / 2983 (0.77%)	22 / 2990 (0.74%)
occurrences causally related to treatment / all	0 / 23	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Disorientation		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Emotional distress		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, visual		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Initial insomnia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Insomnia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mood disorder due to a general medical condition		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nightmare			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Persistent depressive disorder			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post stroke depression			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychogenic tremor			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	0 / 2983 (0.00%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	8 / 2983 (0.27%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Cholecystitis chronic		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	5 / 2983 (0.17%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatic failure		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder perforation		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		

subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis toxic		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatosplenomegaly		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatotoxicity		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Portal hypertension		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver injury		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	9 / 2983 (0.30%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 2983 (0.30%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood cholesterol increased			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood potassium increased			

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure decreased		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	13 / 2983 (0.44%)	14 / 2990 (0.47%)
occurrences causally related to treatment / all	0 / 13	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 0
Blood pressure systolic increased		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood triglycerides increased		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urine present		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Body temperature increased		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
ECG signs of myocardial ischaemia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
ECG signs of ventricular hypertrophy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	4 / 2983 (0.13%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT shortened		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment depression		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcus test positive		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gamma-glutamyltransferase increased		

subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	9 / 2983 (0.30%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate decreased		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter test positive		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A antibody positive		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		
subjects affected / exposed	6 / 2983 (0.20%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Platelet count decreased		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull X-ray abnormal		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin T increased		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
White blood cell count increased			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adjacent segment degeneration			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic haemorrhage			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic ulcer haemorrhage			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	4 / 2983 (0.13%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone fissure		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Burns second degree		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cervical vertebral fracture		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chemical poisoning		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	4 / 2983 (0.13%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Diaphragmatic injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	69 / 2983 (2.31%)	55 / 2990 (1.84%)
occurrences causally related to treatment / all	0 / 77	3 / 59
deaths causally related to treatment / all	0 / 1	0 / 0
Facial bones fracture		
subjects affected / exposed	4 / 2983 (0.13%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated incisional hernia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	4 / 2983 (0.13%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	4 / 2983 (0.13%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle injury		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periprocedural myocardial infarction		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Poisoning		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural fistula		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	5 / 2983 (0.17%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural hypothyroidism		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative delirium		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypotension		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pneumothorax		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	10 / 2983 (0.34%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	8 / 2983 (0.27%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 0
Skull fracture		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Subdural haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tendon injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth fracture		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic arthritis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		

subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic shock		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular access site haematoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Venous injury		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Odontogenic cyst			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery hypoplasia			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	120 / 2983 (4.02%)	118 / 2990 (3.95%)	
occurrences causally related to treatment / all	0 / 136	0 / 126	
deaths causally related to treatment / all	0 / 7	0 / 9	

Angina pectoris		
subjects affected / exposed	196 / 2983 (6.57%)	207 / 2990 (6.92%)
occurrences causally related to treatment / all	0 / 218	0 / 236
deaths causally related to treatment / all	0 / 0	0 / 0
Angina unstable		
subjects affected / exposed	258 / 2983 (8.65%)	247 / 2990 (8.26%)
occurrences causally related to treatment / all	0 / 322	1 / 324
deaths causally related to treatment / all	0 / 1	0 / 1
Anginal equivalent		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	14 / 2983 (0.47%)	8 / 2990 (0.27%)
occurrences causally related to treatment / all	0 / 15	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0
Arrhythmia		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriospasm coronary		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		

subjects affected / exposed	89 / 2983 (2.98%)	94 / 2990 (3.14%)
occurrences causally related to treatment / all	0 / 97	0 / 108
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	11 / 2983 (0.37%)	8 / 2990 (0.27%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	8 / 2983 (0.27%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	7 / 2983 (0.23%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bradycardia		
subjects affected / exposed	8 / 2983 (0.27%)	12 / 2990 (0.40%)
occurrences causally related to treatment / all	0 / 8	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		

subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	4 / 2983 (0.13%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 3
Cardiac disorder		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	65 / 2983 (2.18%)	54 / 2990 (1.81%)
occurrences causally related to treatment / all	0 / 83	1 / 70
deaths causally related to treatment / all	0 / 1	0 / 4
Cardiac failure acute		
subjects affected / exposed	7 / 2983 (0.23%)	9 / 2990 (0.30%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 4
Cardiac failure chronic		
subjects affected / exposed	29 / 2983 (0.97%)	29 / 2990 (0.97%)
occurrences causally related to treatment / all	0 / 30	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		

subjects affected / exposed	9 / 2983 (0.30%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1
Cardio-respiratory arrest		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Cardiac ventricular thrombosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	2 / 2983 (0.07%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 3
Cardiomyopathy		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Chordae tendinae rupture		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	15 / 2983 (0.50%)	11 / 2990 (0.37%)
occurrences causally related to treatment / all	0 / 15	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic left ventricular failure		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery occlusion		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery perforation		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	9 / 2983 (0.30%)	10 / 2990 (0.33%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Cyanosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	3 / 2983 (0.10%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	6 / 2983 (0.20%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular hypertrophy		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve calcification		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	4 / 2983 (0.13%)	11 / 2990 (0.37%)
occurrences causally related to treatment / all	0 / 4	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1
Myocardial infarction		
subjects affected / exposed	4 / 2983 (0.13%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 1
Myocardial ischaemia		
subjects affected / exposed	11 / 2983 (0.37%)	12 / 2990 (0.40%)
occurrences causally related to treatment / all	0 / 11	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	1 / 2983 (0.03%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Postinfarction angina		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	4 / 2983 (0.13%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Rhythm idioventricular		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrhythmia		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	4 / 2983 (0.13%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	3 / 2983 (0.10%)	8 / 2990 (0.27%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	5 / 2983 (0.17%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	7 / 2983 (0.23%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	10 / 2983 (0.34%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic dysfunction		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve disease		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	0 / 2983 (0.00%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ventricular extrasystoles		
subjects affected / exposed	16 / 2983 (0.54%)	11 / 2990 (0.37%)
occurrences causally related to treatment / all	0 / 16	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	3 / 2983 (0.10%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 3
Ventricular hypokinesia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachyarrhythmia		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ventricular tachycardia		

subjects affected / exposed	14 / 2983 (0.47%)	12 / 2990 (0.40%)	
occurrences causally related to treatment / all	0 / 14	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 0	
Wolff-Parkinson-White syndrome			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amnesia			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arachnoid cyst			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basal ganglia haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Basilar artery aneurysm		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain injury		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain oedema		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain stem haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid arteriosclerosis		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery aneurysm		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		

subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	16 / 2983 (0.54%)	15 / 2990 (0.50%)
occurrences causally related to treatment / all	0 / 16	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid sinus syndrome		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cauda equina syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebellar syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery occlusion		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery stenosis		

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral atrophy		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral cyst		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Cerebral infarction		
subjects affected / exposed	3 / 2983 (0.10%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	6 / 2983 (0.20%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral microhaemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral small vessel ischaemic disease		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Cerebrovascular disorder		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chiasma syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		

subjects affected / exposed	3 / 2983 (0.10%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Cranial nerve disorder		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	4 / 2983 (0.13%)	11 / 2990 (0.37%)
occurrences causally related to treatment / all	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Disturbance in attention		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	7 / 2983 (0.23%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	1 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	5 / 2983 (0.17%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysgraphia		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyskinesia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dystonia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolitic stroke		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Epilepsy		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Essential tremor		
subjects affected / exposed	1 / 2983 (0.03%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Extrapyramidal disorder		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paralysis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Frontotemporal dementia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised tonic-clonic seizure		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 3
Haemorrhagic transformation stroke		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotonia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intention tremor		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intercostal neuralgia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		

subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic neuropathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	34 / 2983 (1.14%)	19 / 2990 (0.64%)
occurrences causally related to treatment / all	0 / 36	0 / 21
deaths causally related to treatment / all	0 / 5	0 / 2
Lacunar infarction		
subjects affected / exposed	3 / 2983 (0.10%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	14 / 2983 (0.47%)	12 / 2990 (0.40%)
occurrences causally related to treatment / all	0 / 15	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		

subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Motor dysfunction		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Movement disorder		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myoclonus		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nystagmus		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	5 / 2983 (0.17%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	1 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	6 / 2983 (0.20%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	5 / 6	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	4 / 2983 (0.13%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post stroke epilepsy		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postural tremor		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyramidal tract syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Quadriplegia		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Resting tremor		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Restless legs syndrome		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ruptured cerebral aneurysm		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Sciatica		
subjects affected / exposed	1 / 2983 (0.03%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Simple partial seizures		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Speech disorder		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status epilepticus		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural hygroma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	24 / 2983 (0.80%)	30 / 2990 (1.00%)
occurrences causally related to treatment / all	0 / 27	2 / 33
deaths causally related to treatment / all	0 / 1	0 / 0
Thalamus haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombotic cerebral infarction		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		

subjects affected / exposed	9 / 2983 (0.30%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	15 / 2983 (0.50%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	8 / 15	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	3 / 2983 (0.10%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery occlusion		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery stenosis		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery thrombosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		
subjects affected / exposed	1 / 2983 (0.03%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo CNS origin		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agranulocytosis			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	6 / 2983 (0.20%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia folate deficiency			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of malignant disease			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplastic anaemia			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	25 / 2983 (0.84%)	28 / 2990 (0.94%)
occurrences causally related to treatment / all	0 / 26	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 1
Hypercoagulation		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoprothrombinaemia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	6 / 2983 (0.20%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	4 / 2983 (0.13%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Monocytosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutrophilia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normocytic anaemia		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous haematoma			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	17 / 2983 (0.57%)	19 / 2990 (0.64%)	
occurrences causally related to treatment / all	1 / 17	2 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytosis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness bilateral			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniere's disease			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	6 / 2983 (0.20%)	10 / 2990 (0.33%)	
occurrences causally related to treatment / all	1 / 6	2 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular ataxia			
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis			

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angle closure glaucoma		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blindness cortical		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blindness unilateral		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract		
subjects affected / exposed	25 / 2983 (0.84%)	24 / 2990 (0.80%)
occurrences causally related to treatment / all	0 / 31	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0
Chorioretinal atrophy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic eye disease		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		

subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinal oedema		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exfoliation glaucoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid oedema		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	8 / 2983 (0.27%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Macular cyst		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular degeneration		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Maculopathy		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		
subjects affected / exposed	1 / 2983 (0.03%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Optic nerve compression		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vascular disorder		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Visual acuity reduced		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 2983 (0.03%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haemorrhage			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure haemorrhage			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal polyp		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal prolapse		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon dysplasia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		

subjects affected / exposed	5 / 2983 (0.17%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	3 / 2983 (0.10%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		

subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric polyps		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		

subjects affected / exposed	9 / 2983 (0.30%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	4 / 2983 (0.13%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	0 / 2983 (0.00%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis haemorrhagic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	8 / 2983 (0.27%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage		

subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal vascular malformation haemorrhagic		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		
subjects affected / exposed	7 / 2983 (0.23%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic necrotic pancreatitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhoidal haemorrhage		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		

subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hernial eventration		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal ulcer		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	12 / 2983 (0.40%)	8 / 2990 (0.27%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal ischaemia		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Intestinal polyp		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal strangulation		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	4 / 2983 (0.13%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Lip oedema		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		

subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	0 / 2983 (0.00%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis haemorrhagic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		

subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	4 / 2983 (0.13%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal haemorrhage		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	6 / 2983 (0.20%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stomatitis haemorrhagic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Strangulated umbilical hernia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	4 / 2983 (0.13%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Volvulus of small bowel		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vomiting		

subjects affected / exposed	4 / 2983 (0.13%)	8 / 2990 (0.27%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	3 / 2983 (0.10%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis atopic			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot			
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathic ulcer			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erythema			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Photosensitivity reaction		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus allergic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Purpura		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin burning sensation		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	15 / 2983 (0.50%)	11 / 2990 (0.37%)	
occurrences causally related to treatment / all	0 / 15	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
Azotaemia			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck sclerosis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder trabeculation			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			

subjects affected / exposed	12 / 2983 (0.40%)	17 / 2990 (0.57%)
occurrences causally related to treatment / all	0 / 13	1 / 18
deaths causally related to treatment / all	0 / 1	0 / 1
Crush syndrome		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrectasia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrocalcinosis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	4 / 2983 (0.13%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyuria		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery arteriosclerosis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	10 / 2983 (0.34%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haemorrhage		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal hypertrophy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	8 / 2983 (0.27%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Renal necrosis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric obstruction			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	4 / 2983 (0.13%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	7 / 2983 (0.23%)	4 / 2990 (0.13%)	
occurrences causally related to treatment / all	0 / 8	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinoma			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenomegaly			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hypothyroidism			

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune thyroiditis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes insipidus			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthyroidism			
subjects affected / exposed	3 / 2983 (0.10%)	8 / 2990 (0.27%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	11 / 2983 (0.37%)	7 / 2990 (0.23%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pituitary haemorrhage			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune arthritis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 2983 (0.03%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inclusion body myositis			

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	7 / 2983 (0.23%)	10 / 2990 (0.33%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Joint range of motion decreased		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint swelling		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle atrophy		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rigidity		

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle spasms		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	5 / 2983 (0.17%)	10 / 2990 (0.33%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal stiffness		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myalgia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	19 / 2983 (0.64%)	21 / 2990 (0.70%)
occurrences causally related to treatment / all	0 / 20	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		

subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sympathetic posterior cervical syndrome			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral osteophyte			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal sepsis			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	3 / 2983 (0.10%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Arboviral infection		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerotic gangrene		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial urethritis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		

subjects affected / exposed	4 / 2983 (0.13%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis bacterial		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Candida pneumonia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	7 / 2983 (0.23%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis staphylococcal		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chlamydial infection		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis B		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis C		

subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic tonsillitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon gangrene		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	1 / 2983 (0.03%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dermo-hypodermatitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	4 / 2983 (0.13%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysematous pyelonephritis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	4 / 2983 (0.13%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder abscess		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	4 / 2983 (0.13%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	2 / 2983 (0.07%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis Escherichia coli		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic echinococcosis		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	2 / 2983 (0.07%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Latent syphilis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mastitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site abscess		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	2 / 2983 (0.07%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media acute		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		

subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Peritonsillar abscess		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngotonsillitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal cyst		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	30 / 2983 (1.01%)	40 / 2990 (1.34%)
occurrences causally related to treatment / all	0 / 30	0 / 44
deaths causally related to treatment / all	0 / 1	0 / 3
Pneumonia bacterial		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia chlamydial		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia escherichia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		

subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pneumonia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Postoperative wound infection		
subjects affected / exposed	6 / 2983 (0.20%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary tuberculoma		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		

subjects affected / exposed	2 / 2983 (0.07%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	2 / 2983 (0.07%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	6 / 2983 (0.20%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection bacterial		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection viral		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	3 / 2983 (0.10%)	5 / 2990 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Septic phlebitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		

subjects affected / exposed	4 / 2983 (0.13%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin bacterial infection		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 2983 (0.00%)	2 / 2990 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Tonsillitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	1 / 2983 (0.03%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis of central nervous system		

subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection bacterial		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	10 / 2983 (0.34%)	7 / 2990 (0.23%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	3 / 2983 (0.10%)	3 / 2990 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection enterococcal		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	0 / 2983 (0.00%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2
Viral epiglottitis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral pericarditis		

subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pharyngitis			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral rash			
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	8 / 2983 (0.27%)	8 / 2990 (0.27%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	3 / 2983 (0.10%)	0 / 2990 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glucose tolerance impaired			
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			

subjects affected / exposed	10 / 2983 (0.34%)	11 / 2990 (0.37%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	19 / 2983 (0.64%)	22 / 2990 (0.74%)
occurrences causally related to treatment / all	0 / 21	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 2983 (0.03%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	3 / 2983 (0.10%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	8 / 2983 (0.27%)	6 / 2990 (0.20%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		

subjects affected / exposed	1 / 2983 (0.03%)	4 / 2990 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malnutrition		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	0 / 2983 (0.00%)	1 / 2990 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	61 / 2983 (2.04%)	66 / 2990 (2.21%)
occurrences causally related to treatment / all	0 / 66	0 / 69
deaths causally related to treatment / all	0 / 0	0 / 0
Vitamin B12 deficiency		
subjects affected / exposed	1 / 2983 (0.03%)	0 / 2990 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

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

Non-serious adverse events	Trimetazidine	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1862 / 2983 (62.42%)	1873 / 2990 (62.64%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	91 / 2983 (3.05%)	94 / 2990 (3.14%)	
occurrences (all)	99	101	
Aspartate aminotransferase increased			
subjects affected / exposed	70 / 2983 (2.35%)	73 / 2990 (2.44%)	
occurrences (all)	75	78	
Blood glucose increased			
subjects affected / exposed	27 / 2983 (0.91%)	48 / 2990 (1.61%)	
occurrences (all)	28	52	
Blood pressure increased			
subjects affected / exposed	49 / 2983 (1.64%)	42 / 2990 (1.40%)	
occurrences (all)	54	43	
Blood triglycerides increased			
subjects affected / exposed	57 / 2983 (1.91%)	51 / 2990 (1.71%)	
occurrences (all)	68	54	
Vascular disorders			
Hypertension			
subjects affected / exposed	330 / 2983 (11.06%)	360 / 2990 (12.04%)	
occurrences (all)	394	412	
Hypotension			
subjects affected / exposed	62 / 2983 (2.08%)	54 / 2990 (1.81%)	
occurrences (all)	74	57	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	163 / 2983 (5.46%)	135 / 2990 (4.52%)	
occurrences (all)	183	154	
Sinus bradycardia			
subjects affected / exposed	40 / 2983 (1.34%)	55 / 2990 (1.84%)	
occurrences (all)	51	57	
Ventricular extrasystoles			
subjects affected / exposed	67 / 2983 (2.25%)	71 / 2990 (2.37%)	
occurrences (all)	69	75	

Nervous system disorders			
Dizziness			
subjects affected / exposed	49 / 2983 (1.64%)	52 / 2990 (1.74%)	
occurrences (all)	53	55	
Headache			
subjects affected / exposed	74 / 2983 (2.48%)	78 / 2990 (2.61%)	
occurrences (all)	85	88	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	66 / 2983 (2.21%)	38 / 2990 (1.27%)	
occurrences (all)	67	38	
Thrombocytopenia			
subjects affected / exposed	45 / 2983 (1.51%)	44 / 2990 (1.47%)	
occurrences (all)	57	50	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	58 / 2983 (1.94%)	63 / 2990 (2.11%)	
occurrences (all)	70	77	
Oedema peripheral			
subjects affected / exposed	45 / 2983 (1.51%)	60 / 2990 (2.01%)	
occurrences (all)	52	64	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	32 / 2983 (1.07%)	49 / 2990 (1.64%)	
occurrences (all)	36	51	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	55 / 2983 (1.84%)	62 / 2990 (2.07%)	
occurrences (all)	57	63	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	40 / 2983 (1.34%)	49 / 2990 (1.64%)	
occurrences (all)	41	49	
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed occurrences (all)	43 / 2983 (1.44%) 50	61 / 2990 (2.04%) 71	
Infections and infestations			
Bronchitis			
subjects affected / exposed	75 / 2983 (2.51%)	61 / 2990 (2.04%)	
occurrences (all)	82	74	
Influenza			
subjects affected / exposed	68 / 2983 (2.28%)	77 / 2990 (2.58%)	
occurrences (all)	87	96	
Nasopharyngitis			
subjects affected / exposed	66 / 2983 (2.21%)	71 / 2990 (2.37%)	
occurrences (all)	75	103	
Upper respiratory tract infection			
subjects affected / exposed	44 / 2983 (1.48%)	51 / 2990 (1.71%)	
occurrences (all)	77	89	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	103 / 2983 (3.45%)	112 / 2990 (3.75%)	
occurrences (all)	109	117	
Hyperglycaemia			
subjects affected / exposed	62 / 2983 (2.08%)	64 / 2990 (2.14%)	
occurrences (all)	68	68	
Hypertriglyceridaemia			
subjects affected / exposed	117 / 2983 (3.92%)	138 / 2990 (4.62%)	
occurrences (all)	120	151	
Type 2 diabetes mellitus			
subjects affected / exposed	138 / 2983 (4.63%)	120 / 2990 (4.01%)	
occurrences (all)	143	125	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 April 2014	Amendment n°2 was issued before the recruitment was started and required a change to the ICF. It was applicable in all centres of the study (all countries) and mainly concerned: <ul style="list-style-type: none">- The removal of a treatment arm with a higher dose of trimetazidine (70 mg b.i.d.).- Patients with moderate renal failure could enter the study with dosage adjustment.- The number of required events for the primary efficacy endpoint (reduced from 2390 to 1363 and total number of included patients reduced from 10 300 to 5800).- The number of participating countries (reduced from 54 to 27 and number of centres from about 800 to about 400).- The update of planned study initiation and completion dates.- The measurement of troponin before and after PCI, limited to elective PCI.- The addition of a non inclusion criterion: time interval between PCI and inclusion > 30 days.
30 November 2015	Amendment n°3 was applicable in all centres of the study (all countries) and mainly concerned: <ul style="list-style-type: none">- The clarification of some selection and inclusion criteria: the worst severity of angina pectoris within the previous 4 weeks was expected to be reported at the selection visit and the requirement of stability of antianginal therapy at inclusion was clarified.- The modification of the section named Adverse Events of Interest, to introduce EIs not reported as AEs.- The change in the reporting rules of AEs occurring between the randomization of the patient and the first administration of the IMP.
10 May 2017	-Amendment n°4 was applicable in all centres of the study (all countries) and mainly concerned: <ul style="list-style-type: none">- The clarification on the management of blinding systems.- The clarification on 2 Events of Interest (neurological symptoms and coagulation disorders).- The modification of the specific storage conditions of the IMP for Belarus.
04 February 2019	Amendment No. 5 was applicable in all centres (all countries) and mainly concerned: Correction of Appendix 5 of the study protocol concerning the Clinical Classification of Chest Pain.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported