Clinical trial results:
A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer

Summary

EudraCT number	2008-008004-41
Trial protocol	GB NL SE FR DE BE ES IT GR
Global end of trial date	25 May 2017

Results information

Result version number	v1 (current)
This version publication date	09 June 2018
First version publication date	09 June 2018

Trial information

Trial identification

Sponsor protocol code	COU-AA-302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00887198
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	1000 U.S. Route 202 South, Raritan, NJ, United States, 08869
Public contact	Clinical Registry group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.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	31 March 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to compare the clinical benefit of abiraterone acetate plus prednisone to placebo plus prednisone in men with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC), who were asymptomatic or mildly symptomatic.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Known instances of nonconformance were documented and are not considered to have had an impact on the overall conclusions of this study. Safety was evaluated throughout the study and included adverse events (AEs), serious adverse events (SAEs), routine chemical test (Hematology, chemistry, coagulation, urinalysis and Serum Lipids), vital signs, Electrocardiograms, Physical examinations and body weight.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 April 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 132
Country: Number of subjects enrolled	Belgium: 42
Country: Number of subjects enrolled	Canada: 100
Country: Number of subjects enrolled	France: 53
Country: Number of subjects enrolled	Germany: 78
Country: Number of subjects enrolled	Greece: 14
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Netherlands: 30
Country: Number of subjects enrolled	Spain: 45
Country: Number of subjects enrolled	Sweden: 17
Country: Number of subjects enrolled	United Kingdom: 98
Country: Number of subjects enrolled	United States: 472
Worldwide total number of subjects	1088
EEA total number of subjects	384

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)	290
From 65 to 84 years	741
85 years and over	57

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 1088 subjects were randomized out of which 1082 (542 in Abiraterone Acetate [AA] group and 540 in placebo group) received the study drug. After Amendment 3, subjects receiving placebo and after amendment 4 those who were discontinued from placebo, but continuing in long-term follow up were crossed over to abiraterone acetate treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Abiraterone Acetate + Prednisone (AAP)

Arm description:

Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

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

Dosage and administration details:

Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily.

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

Dosage and administration details:

Subjects received prednisone 5 mg tablet orally twice daily, from Day 1 along with 1000 mg abiraterone acetate tablets (as 4*250 mg tablets) orally once daily.

Arm title	Placebo

Arm description:

Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.

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:

Subjects received 4 tablets of placebo matching to Abiraterone Acetate 250 mg orally along with prednisone 5 mg tablet orally twice daily.

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

Dosage and administration details:

Subjects received prednisone 5 mg tablet orally twice daily, from Day 1 along with 1000 mg abiraterone acetate tablets (as 4*250 mg tablets) orally once daily.

Number of subjects in period 1	Abiraterone Acetate + Prednisone (AAP)	Placebo
Started	546	542
Treated	542	540
Total crossover to AA	0	93
Completed	0	0
Not completed	546	542
Consent withdrawn by subject	41	56
Cross-over to aa	-	51
Lost to follow-up	1	-
Adverse event, non-fatal	50	33
Randomized, Not treated	4	2
Ongoing	42	-
Unspecified	42	30
Progressive disease	366	370

Baseline characteristics

Reporting groups	
Reporting group title	Abiraterone Acetate + Prednisone (AAP)
Reporting group description:	
Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.	

Reporting group values	Abiraterone Acetate + Prednisone (AAP)	Placebo	Total
Number of subjects	546	542	1088
Title for AgeCategorical Units: subjects			
Adults (18-64 years)	135	155	290
From 65 to 84 years	383	358	741
85 years and over	28	29	57
Title for AgeContinuous Units: years			
arithmetic mean	70.5	70.1	
standard deviation	± 8.8	± 8.72	-
Title for Gender Units: subjects			
Male	546	542	1088

End points

End points reporting groups

Reporting group title	Abiraterone Acetate + Prednisone (AAP)
Reporting group description:	
Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.	
Subject analysis set title	Placebo to Abiraterone Acetate (AA)
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Subjects who were originally assigned to placebo were later on switched to 1,000 milligram (mg) abiraterone acetate tablet (as 4*250 mg tablets) along with prednisone 5 mg tablet.	

Primary: Overall Survival

End point title	Overall Survival
End point description:	
Overall survival is defined as the time from randomization to date of death from any cause. Intent-to-treat (ITT) population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received.	
End point type	Primary
End point timeframe:	
From randomization (Day 1) up to end of study (Month 60)	

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	546	542		
Units: Months				
median (confidence interval 95%)	34.66 (32.72 to 36.80)	30.29 (28.65 to 33.28)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Abiraterone Acetate + Prednisone (AAP) v Placebo

Number of subjects included in analysis	1088
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0033
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.806
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.697
upper limit	0.931

Primary: Radiographic Progression-free Survival (rPFS)

End point title	Radiographic Progression-free Survival (rPFS)

End point description:

The rPFS was defined as time from randomization to the occurrence of one of the following a subject was considered to have progressed by bone scan if a) the first bone scan with >= 2 new lesions compared to baseline was observed in less than (<) 12 weeks from randomization and was confirmed by a second bone scan taken >=6 weeks later showing >=2 additional new lesions (a total of >=4 new lesions compared to baseline), b) the first bone scan with >=2 new lesions compared to baseline was observed in >=12 weeks from randomization and the new lesions were verified on the next bone scan >=6 weeks later; 2) progression of soft tissue lesions measured by computerized tomography (CT) or MRI 3) death from any cause. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received. Here "99999" indicates data was not estimable due to insufficient number of subjects who had the event.

End point type	Primary

End point timeframe:

From randomization (Day 1) up to first radiographic progression or cutoff date (Month 18)

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	546	542		
Units: Months				
median (confidence interval 95%)	99999 (11.66 to 99999)	8.28 (8.12 to 8.54)		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Abiraterone Acetate + Prednisone (AAP) v Placebo

Number of subjects included in analysis	1088
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.425
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.347
upper limit	0.522

Secondary: Time to Opiate Use for Prostate Cancer Pain

End point title	Time to Opiate Use for Prostate Cancer Pain

End point description:

The time interval from the date of randomization to the date of opiate use for cancer pain. Subjects who have no opiate use at the time of analysis were censored at the last known date of no opiate use for cancer pain. Subjects with no assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received.

End point type	Secondary

End point timeframe:

From randomization (Day 1) up to first opiate use or end of study (Month 60)

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	546	542		
Units: Months				
median (confidence interval 95%)	33.28 (30.23 to 39.75)	23.39 (20.27 to 27.53)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Initiation of Cytotoxic Chemotherapy

End point title	Time to Initiation of Cytotoxic Chemotherapy

End point description:

The time interval from the date of randomization to the date of initiation of cytotoxic chemotherapy for prostate cancer. Subjects who had no cytotoxic chemotherapy administration at the time of analysis were censored at the last known date when no cytotoxic chemotherapy was administered. Subjects with no assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual

treatment received. Here "99999" indicates data was not estimable due to insufficient number of subjects who had the event.

End point type	Secondary

End point timeframe:

From randomization (Day 1) up to initiation of cytotoxic chemotherapy or cutoff date (Month 18)

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	546	542		
Units: Months				
median (confidence interval 95%)	25.17 (23.26 to 99999)	16.82 (14.55 to 19.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Deterioration in Eastern Cooperative Oncology Group (ECOG) Performance Score by >=1 Point

End point title	Time to Deterioration in Eastern Cooperative Oncology Group (ECOG) Performance Score by >=1 Point

End point description:

The time interval from the date of randomization to the first date at which there was at least a 1 grade change (worsening) in the ECOG performance status grade. Subjects who had no deterioration in ECOG performance status grade at the time of the analysis were censored at the last known date of no deterioration. ECOG is a 5-point scale, where 0=Fully active, 1=Ambulatory, carry out work of sedentary nature, 2=Ambulatory, capable of all self-care, 3=Capable of limited self-care, confined to bed or chair more than 50% of waking hours, 4=Completely disabled, no self-care, totally confined to bed or chair, 5=Dead. Subjects with no assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received.

End point type	Secondary

End point timeframe:

From randomization (Day 1) up to first radiographic progression or cutoff date (Month 18)

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	546	542		
Units: Months				
median (confidence interval 95%)	12.29 (11.33 to 14.29)	10.87 (9.49 to 11.76)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Prostate-specific Antigen (PSA) Progression

End point title	Time to Prostate-specific Antigen (PSA) Progression

End point description:

The time interval from the date of randomization to the date of PSA progression as defined in the protocol-specific prostate cancer Working Group 2 (PCWG2) criteria. A subjects was considered to have a PSA progression if the PSA level had a 25 percent (%) or greater increase from nadir and an absolute increase of 2 nanogram/milliliter ((ng/mL) or more, which is confirmed by a second value obtained in 3 or more weeks. Subjects who had no PSA progression at the time of the analysis were censored at the last known date of no PSA progression. Subjects with no on-study PSA assessment or no baseline PSA assessment were censored at the date of randomization. ITT population included all the randomized subjects who were classified according to their assigned treatment group, regardless of the actual treatment received.

End point type	Secondary

End point timeframe:

From randomization (Day 1) up to date of PSA progerssion or cutoff date (Month 18)

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	546	542		
Units: Months				
median (confidence interval 95%)	11.07 (8.51 to 11.24)	5.55 (5.39 to 5.59)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events

End point title	Number of Subjects With Treatment Emergent Adverse Events

End point description:

An adverse event (AE) was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. A serious adverse event (SAE) was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent were events between administration of study drug and up to 30 days after last dose of study drug that were absent before treatment or that worsened relative to pre-treatment state. Safety analysis set included all subjects in the randomized population who received any study drug.

End point type	Secondary

End point timeframe:

From first dose of study drug up to 30 days after the last dose of study drug

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo	Placebo to Abiraterone Acetate (AA)	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	542	540	93	
Units: Subjects				
With Treatment-Emergent Adverse Events	541	524	93	
With Treatment-Emergent Serious Adverse Events	208	148	39	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Plasma Concentrations of Abiraterone

End point title	Mean Plasma Concentrations of Abiraterone

End point description:

End point type	Secondary

End point timeframe:

Up to Cycle 5, Day 1

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[1]	0[2]		
Units: nanogram per milliliter (ng/ml)				
arithmetic mean (standard deviation)	()	()		

Notes:

[1] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[2] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Plasma Concentrations of Abiraterone

End point title	Maximum Plasma Concentrations of Abiraterone

End point description:

End point type	Secondary

End point timeframe:

Up to Cycle 5, Day 1

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[3]	0[4]		
Units: nanogram per milliliter (ng/ml)				
arithmetic mean (standard deviation)	()	()		

Notes:

[3] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[4] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-time Curve from Time 0 to Time the Last Quantifiable Concentration of Abiraterone (AUC[0-infinity])

End point title	Area Under the Plasma Concentration-time Curve from Time 0 to Time the Last Quantifiable Concentration of Abiraterone (AUC[0-infinity])

End point description:

The AUC (0-infinity) is the area under the plasma concentration-time curve from time zero to infinite time, calculated as the sum of AUC(last) and C(last)/lambda(z); wherein AUC(last) is area under the plasma concentration-time curve from time zero to last quantifiable time, C(last) is the last observed quantifiable concentration, and lambda(z) is elimination rate constant.

End point type	Secondary

End point timeframe:

Up to Cycle 5, Day 1

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[5]	0[6]		
Units: nanogram*hour per milliliter				
arithmetic mean (standard deviation)	()	()		

Notes:

[5] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[6] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Secondary: Elimination Half-Life (t1/2)

End point title	Elimination Half-Life (t1/2)

End point description:

The elimination half-life (t1/2) is the time measured for the plasma concentration to decrease by 1 half to its original concentration. It is associated with the terminal slope of the semi logarithmic drug concentration-time curve, and is calculated as 0.693/lambda(z).

End point type	Secondary

End point timeframe:

Up to Cycle 5, Day 1

End point values	Abiraterone Acetate + Prednisone (AAP)	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[7]	0[8]		
Units: Hours				
arithmetic mean (standard deviation)	()	()		

Notes:

[7] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

[8] - Data was not reported as non-compartmental analysis was not performed due to sparse sampling.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of study drug up to 30 days after the last dose of study drug	
Adverse event reporting additional description:	
Safety analysis set included all subjects in the randomized population who received any study drug.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups	
Reporting group title	Abiraterone Acetate + Prednisone (AAP)
Reporting group description:	
Subjects received 1000 milligram (mg) abiraterone acetate tablets (as 4*250 mg tablets) orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.	
Reporting group title	Placebo to AA
Reporting group description:	
Subjects who were originally assigned to placebo were later on switched to 1,000 milligram (mg) abiraterone acetate tablet (as 4*250 mg tablets) along with prednisone 5 mg tablet.	
Reporting group title	Placebo
Reporting group description:	
Subjects received placebo matched to abiraterone acetate tablets orally once daily along with prednisone 5 mg tablet orally twice daily, from Day 1, Cycle1 (each cycle consist of 28 days) up to radiographic progression of disease and/or unequivocal clinical progression.	

Serious adverse events	Abiraterone Acetate + Prednisone (AAP)	Placebo to AA	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	215 / 542 (39.67%)	40 / 93 (43.01%)	156 / 540 (28.89%)
number of deaths (all causes)	352	24	387
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-Cell Type Acute Leukaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal Cell Carcinoma			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Cancer			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central Nervous System Lymphoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Cancer			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Colorectal Cancer			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Cancer			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Adenocarcinoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Neoplasm			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Neoplasm Malignant			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Neoplasm of Ampulla of Vater			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Meninges			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic Pain			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatic Carcinoma			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Cancer			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Arterial Thrombosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	1 / 4	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism Venous			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Embolism			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous Thrombosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Aortic Valve Replacement			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemotherapy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee Arthroplasty			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatectomy			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral Prostatectomy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter Related Complication			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Disease Progression			
subjects affected / exposed	8 / 542 (1.48%)	6 / 93 (6.45%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	1 / 8	0 / 6	0 / 4
deaths causally related to treatment / all	1 / 5	0 / 3	0 / 2
Fatigue			
subjects affected / exposed	2 / 542 (0.37%)	2 / 93 (2.15%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait Disturbance			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 1
Hypothermia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal Inflammation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-Organ Failure			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	1 / 1	0 / 1	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance Status Decreased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic Inflammatory Response Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Erectile Dysfunction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic Haemorrhage			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dyspnoea			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences causally related to treatment / all	2 / 2	0 / 0	6 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hypoxia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	10 / 542 (1.85%)	1 / 93 (1.08%)	12 / 540 (2.22%)
occurrences causally related to treatment / all	4 / 10	0 / 2	4 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar Cyst			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed Suicide			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Confusional State			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	5 / 5	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase Increased			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	3 / 3	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Creatinine Increased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Uric Acid Increased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonoscopy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram QT Prolonged			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram St Segment Depression			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase Increased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet Count Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Animal Scratch			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Perforation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract Operation Complication			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Radiation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Dislocation			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Radiation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Anastomotic Leak			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implantable Defibrillator Malfunction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Narcotic Intoxication			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubic Rami Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skeletal Injury			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft Tissue Injury			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	0 / 542 (0.00%)	2 / 93 (2.15%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haemorrhage			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Rupture			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic Vertebral Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia Fracture			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Myocardial Infarction			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	3 / 6	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	11 / 542 (2.03%)	0 / 93 (0.00%)	8 / 540 (1.48%)
occurrences causally related to treatment / all	5 / 13	0 / 0	7 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block Second Degree			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bifascicular Block			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Cardiac Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conduction Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ischaemic Cardiomyopathy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			

subjects affected / exposed	4 / 542 (0.74%)	2 / 93 (2.15%)	5 / 540 (0.93%)
occurrences causally related to treatment / all	2 / 4	0 / 2	2 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Myocardial Ischaemia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachyarrhythmia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Amyotrophic Lateral Sclerosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Haemorrhage			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Infarction			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Cerebral Ischaemia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	3 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 6	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 2	0 / 0	1 / 1
Convulsion			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic Stroke			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of Consciousness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory Impairment			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine with Aura			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoparesis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Root Compression			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological Symptom			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	0 / 7	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 6	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope Vasovagal			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vith Nerve Paralysis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	8 / 542 (1.48%)	1 / 93 (1.08%)	6 / 540 (1.11%)
occurrences causally related to treatment / all	0 / 8	0 / 1	6 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated Intravascular Coagulation			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Febrile Neutropenia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphopenia			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences causally related to treatment / all	0 / 3	0 / 0	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular Perforation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal Haemorrhagic			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food Poisoning			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis Erosive			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Necrosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Ischaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Mass			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatic Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pancreatitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Necrotising			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices Oesophageal			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile Duct Obstruction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Actinic Keratosis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Lesion			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Bladder Mass			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Obstruction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Spasm			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Tamponade			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Bladder			
subjects affected / exposed	0 / 542 (0.00%)	2 / 93 (2.15%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Ureteric			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	11 / 542 (2.03%)	3 / 93 (3.23%)	5 / 540 (0.93%)
occurrences causally related to treatment / all	1 / 14	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Urinary Tract			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive Uropathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pollakiuria			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Acute			

subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Impairment			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric Obstruction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric Stenosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Obstruction			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Incontinence			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal Insufficiency			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	0 / 8	0 / 1	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Pain			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank Pain			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Groin Pain			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw Cyst			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Swelling			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
subjects affected / exposed	1 / 542 (0.18%)	2 / 93 (2.15%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological Fracture			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Column Stenosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal Abscess			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary Sepsis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis Infective			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter Gastroenteritis			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 542 (0.37%)	2 / 93 (2.15%)	3 / 540 (0.56%)
occurrences causally related to treatment / all	1 / 2	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal Infection			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Urinary Tract Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Abscess			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 6	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Salmonella			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival Infection			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Zoster			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Exacerbation of Chronic Obstructive Airways Disease			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Necrotising Fasciitis			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae Virus Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	10 / 542 (1.85%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	3 / 12	0 / 1	2 / 4
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Pneumonia Influenzal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Staphylococcal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Wound Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal Bacteraemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	7 / 542 (1.29%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	2 / 8	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	1 / 4	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	14 / 542 (2.58%)	5 / 93 (5.38%)	4 / 540 (0.74%)
occurrences causally related to treatment / all	8 / 17	0 / 8	1 / 5
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Urinary Tract Infection Bacterial			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	2 / 6	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to Thrive			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid Retention			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperuricaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Abiraterone Acetate + Prednisone (AAP)	Placebo to AA	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	540 / 542 (99.63%)	88 / 93 (94.62%)	524 / 540 (97.04%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acoustic Neuroma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Acrochordon			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	2	0	4
Atypical Fibroxanthoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Basal Cell Carcinoma			
subjects affected / exposed	9 / 542 (1.66%)	2 / 93 (2.15%)	10 / 540 (1.85%)
occurrences (all)	10	2	13
Benign Neoplasm of Skin			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bladder Neoplasm			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bowen's Disease			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cancer Pain			
subjects affected / exposed	14 / 542 (2.58%)	0 / 93 (0.00%)	16 / 540 (2.96%)
occurrences (all)	18	0	26
Chronic Lymphocytic Leukaemia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Colon Adenoma			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Cystic Lymphangioma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Haemangioma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Keratoacanthoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	4
Lip Neoplasm Malignant Stage			

Unspecified			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Lipoma			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	4	1	3
Malignant Melanoma			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Melanocytic Naevus			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	0	1	1
Metastases to Bone			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Metastatic Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Neoplasm Malignant			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Neurilemmoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Rectal Cancer			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Renal Cell Carcinoma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Seborrhoeic Keratosis			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	7	0	4
Skin Papilloma			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	3	0	4

Spinal Cord Neoplasm			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Squamous Cell Carcinoma			
subjects affected / exposed	11 / 542 (2.03%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	16	3	4
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Tongue Neoplasm Malignant Stage Unspecified			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Transitional Cell Carcinoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Tumour Pain			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Vocal Cord Neoplasm			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Angiodysplasia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Aortic Aneurysm			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Aortic Arteriosclerosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Arterial Thrombosis Limb			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Capillary Fragility			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Circulatory Collapse			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Deep Vein Thrombosis			
subjects affected / exposed	8 / 542 (1.48%)	1 / 93 (1.08%)	6 / 540 (1.11%)
occurrences (all)	8	1	6
Flushing			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	9	0	5
Gastrointestinal Arteriovenous Malformation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	22 / 542 (4.06%)	1 / 93 (1.08%)	6 / 540 (1.11%)
occurrences (all)	32	1	6
Haemorrhage			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Hot Flush			
subjects affected / exposed	124 / 542 (22.88%)	6 / 93 (6.45%)	100 / 540 (18.52%)
occurrences (all)	153	6	122
Hypertension			
subjects affected / exposed	129 / 542 (23.80%)	6 / 93 (6.45%)	73 / 540 (13.52%)
occurrences (all)	182	8	94
Hypotension			
subjects affected / exposed	24 / 542 (4.43%)	3 / 93 (3.23%)	16 / 540 (2.96%)
occurrences (all)	24	4	19
Intermittent Claudication			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Lymphoedema			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1

Microangiopathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Orthostatic Hypotension			
subjects affected / exposed	5 / 542 (0.92%)	2 / 93 (2.15%)	4 / 540 (0.74%)
occurrences (all)	5	2	4
Pallor			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Peripheral Ischaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Thrombophlebitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Thrombophlebitis Superficial			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Varicose Vein			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	1	0	4
Vein Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Venous Thrombosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1

Venous Thrombosis Limb			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Cataract Operation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	2
Knee Arthroplasty			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Skin Neoplasm Excision			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Transurethral Prostatectomy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Ureteral Stent Insertion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Wisdom Teeth Removal			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Abasia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Adverse Drug Reaction			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Asthenia			
subjects affected / exposed	46 / 542 (8.49%)	1 / 93 (1.08%)	46 / 540 (8.52%)
occurrences (all)	65	1	66
Axillary Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Catheter Related Complication			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	0	0	7
Catheter Site Erythema			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Catheter Site Haematoma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Catheter Site Haemorrhage			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Catheter Site Inflammation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Catheter Site Pain			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	8
Chest Discomfort			
subjects affected / exposed	10 / 542 (1.85%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	10	0	8
Chest Pain			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	2	1	8
Chills			
subjects affected / exposed	15 / 542 (2.77%)	2 / 93 (2.15%)	14 / 540 (2.59%)
occurrences (all)	17	2	17
Cyst			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	2
Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Disease Progression			
subjects affected / exposed	3 / 542 (0.55%)	2 / 93 (2.15%)	1 / 540 (0.19%)
occurrences (all)	3	2	1
Energy Increased			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Extravasation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Face Oedema			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	6	0	4
Facial Pain			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Fatigue			
subjects affected / exposed	243 / 542 (44.83%)	27 / 93 (29.03%)	200 / 540 (37.04%)
occurrences (all)	448	35	314
Feeling Abnormal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Feeling Cold			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	2	1	1
Feeling Hot			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	2
Feeling Jittery			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	2
Gait Disturbance			
subjects affected / exposed	10 / 542 (1.85%)	0 / 93 (0.00%)	10 / 540 (1.85%)
occurrences (all)	12	0	12
General Physical Health Deterioration			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	8	0	3
Generalised Oedema			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Hangover			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Hernia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Hernia Pain			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	3	1	0
Hunger			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hyperthermia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Hypothermia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Impaired Healing			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Implant Site Inflammation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Implant Site Reaction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Inflammation			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Influenza Like Illness			
subjects affected / exposed	20 / 542 (3.69%)	4 / 93 (4.30%)	10 / 540 (1.85%)
occurrences (all)	27	4	14
Infusion Site Bruising			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Injection Site Bruising			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Injection Site Haematoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Injection Site Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Injection Site Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Injection Site Reaction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Irritability			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	7	0	5
Local Swelling			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Localised Oedema			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	5	0	1
Malaise			
subjects affected / exposed	10 / 542 (1.85%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	12	0	7
Mass			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	2	1	2
Mucosal Inflammation			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	9	0	2
Multi-Organ Failure			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Nodule			

subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	6	0	1
Non-Cardiac Chest Pain			
subjects affected / exposed	13 / 542 (2.40%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	13	1	14
Oedema Peripheral			
subjects affected / exposed	148 / 542 (27.31%)	22 / 93 (23.66%)	119 / 540 (22.04%)
occurrences (all)	269	24	198
Pain			
subjects affected / exposed	27 / 542 (4.98%)	0 / 93 (0.00%)	16 / 540 (2.96%)
occurrences (all)	28	0	18
Papillitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pelvic Mass			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Performance Status Decreased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Peripheral Coldness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Pitting Oedema			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	4	0	6
Puncture Site Reaction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	54 / 542 (9.96%)	5 / 93 (5.38%)	33 / 540 (6.11%)
occurrences (all)	69	7	45
Sensation of Pressure			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Suprapubic Pain			

subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Temperature Intolerance			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Thirst			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Venipuncture Site Swelling			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Vessel Puncture Site Haematoma			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Wound Necrosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Xerosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Immune system disorders			
Contrast Media Allergy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Drug Hypersensitivity			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hypersensitivity			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	3	0	4
Seasonal Allergy			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	5 / 540 (0.93%)
occurrences (all)	8	2	5
Reproductive system and breast disorders			

Balanitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Breast Mass			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Breast Pain			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Breast Tenderness			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	4
Epididymal Cyst			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Erectile Dysfunction			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	9	0	2
Genital Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Nipple Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Oedema Genital			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Penile Discharge			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Penile Oedema			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Penile Pain			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	6	0	2

Penile Size Reduced			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Perineal Pain			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	7	0	3
Prostate Induration			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Prostatic Obstruction			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Prostatic Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Prostatism			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Prostatitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Scrotal Haematocoele			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Scrotal Oedema			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Scrotal Pain			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	3	1	1
Testicular Atrophy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Testicular Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Testicular Pain			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	8	0	2
Testicular Swelling			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	4
Testis Discomfort			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	5	0	1
Atelectasis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	3	0	3
Bronchopneumopathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bronchospasm			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Chest Discomfort			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Chest Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	3 / 542 (0.55%)	2 / 93 (2.15%)	4 / 540 (0.74%)
occurrences (all)	4	2	4
Cough			

subjects affected / exposed	106 / 542 (19.56%)	11 / 93 (11.83%)	74 / 540 (13.70%)
occurrences (all)	146	14	92
Dry Throat			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Dysphonia			
subjects affected / exposed	17 / 542 (3.14%)	0 / 93 (0.00%)	6 / 540 (1.11%)
occurrences (all)	18	0	6
Dyspnoea			
subjects affected / exposed	71 / 542 (13.10%)	7 / 93 (7.53%)	52 / 540 (9.63%)
occurrences (all)	116	8	74
Dyspnoea Exertional			
subjects affected / exposed	16 / 542 (2.95%)	0 / 93 (0.00%)	13 / 540 (2.41%)
occurrences (all)	21	0	13
Emphysema			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	1	0	3
Epistaxis			
subjects affected / exposed	12 / 542 (2.21%)	1 / 93 (1.08%)	9 / 540 (1.67%)
occurrences (all)	13	1	10
Haemoptysis			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	2	1	0
Hiccups			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Increased Bronchial Secretion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Increased Upper Airway Secretion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	3
Interstitial Lung Disease			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Lung Infiltration			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Nasal Congestion			
subjects affected / exposed	20 / 542 (3.69%)	0 / 93 (0.00%)	14 / 540 (2.59%)
occurrences (all)	26	0	18
Nasal Mucosal Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Nasal Septum Deviation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Orthopnoea			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Paranasal Sinus Hypersecretion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Pharyngeal Erythema			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pharyngolaryngeal Discomfort			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Pharyngolaryngeal Pain			
subjects affected / exposed	21 / 542 (3.87%)	4 / 93 (4.30%)	13 / 540 (2.41%)
occurrences (all)	29	4	14
Pleural Effusion			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	5	0	3
Pleuritic Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Pneumonia Aspiration			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Pneumothorax			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Postnasal Drip			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	3	0	3
Productive Cough			
subjects affected / exposed	17 / 542 (3.14%)	0 / 93 (0.00%)	11 / 540 (2.04%)
occurrences (all)	23	0	13
Prolonged Expiration			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pulmonary Embolism			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	8 / 540 (1.48%)
occurrences (all)	5	0	9
Pulmonary Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pulmonary Hypertension			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Rales			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	4	0	4
Respiratory Distress			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Respiratory Failure			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Respiratory Tract Congestion			

subjects affected / exposed	10 / 542 (1.85%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	14	0	4
Respiratory Tract Haemorrhage			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	12	0	4
Rhinitis Allergic			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Rhinorrhoea			
subjects affected / exposed	13 / 542 (2.40%)	0 / 93 (0.00%)	9 / 540 (1.67%)
occurrences (all)	14	0	9
Rhonchi			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Sinus Congestion			
subjects affected / exposed	9 / 542 (1.66%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences (all)	21	1	4
Sinus Polyp			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Sleep Apnoea Syndrome			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Sputum Discoloured			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Tachypnoea			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Throat Irritation			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Tracheal Pain			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Congestion			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Wheezing			
subjects affected / exposed	8 / 542 (1.48%)	2 / 93 (2.15%)	7 / 540 (1.30%)
occurrences (all)	9	2	7
Psychiatric disorders			
Abnormal Dreams			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Affect Lability			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Affective Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Aggression			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Agitation			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	4	0	6
Alcoholism			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	30 / 542 (5.54%)	4 / 93 (4.30%)	23 / 540 (4.26%)
occurrences (all)	38	4	25
Bipolar Disorder			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Bulimia Nervosa			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1

Claustrophobia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Confusional State			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	10 / 540 (1.85%)
occurrences (all)	7	2	13
Delirium			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Depressed Mood			
subjects affected / exposed	12 / 542 (2.21%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	16	1	8
Depression			
subjects affected / exposed	32 / 542 (5.90%)	3 / 93 (3.23%)	19 / 540 (3.52%)
occurrences (all)	41	3	20
Disorientation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Elevated Mood			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Emotional Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Hallucination, Visual			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Impatience			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	82 / 542 (15.13%)	5 / 93 (5.38%)	62 / 540 (11.48%)
occurrences (all)	112	5	67
Libido Decreased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1

Loss of Libido			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Mania			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Mental Disorder			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Mental Disorder Due to A General Medical Condition			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Middle Insomnia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Mood Altered			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	8 / 540 (1.48%)
occurrences (all)	9	0	8
Mood Swings			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	1	0	4
Nervousness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Panic Attack			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pressure of Speech			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Seasonal Affective Disorder			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Sleep Disorder			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	6	1	7
Somnambulism			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Stress			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Suicidal Ideation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Suspiciousness			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Tearfulness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Investigations			
Activated Partial Thromboplastin Time Prolonged			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Activated Partial Thromboplastin Time Shortened			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Alanine Aminotransferase Increased			
subjects affected / exposed	70 / 542 (12.92%)	3 / 93 (3.23%)	26 / 540 (4.81%)
occurrences (all)	167	6	40
Aspartate Aminotransferase Increased			
subjects affected / exposed	63 / 542 (11.62%)	4 / 93 (4.30%)	25 / 540 (4.63%)
occurrences (all)	114	4	35
Blood Alkaline Phosphatase Increased			

subjects affected / exposed	22 / 542 (4.06%)	4 / 93 (4.30%)	25 / 540 (4.63%)
occurrences (all)	43	4	36
Blood Amylase Increased			
subjects affected / exposed	8 / 542 (1.48%)	2 / 93 (2.15%)	4 / 540 (0.74%)
occurrences (all)	19	7	10
Blood Bicarbonate Decreased			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	5	1	2
Blood Calcium Decreased			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Blood Calcium Increased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Blood Chloride Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Blood Cortisol Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Blood Creatinine Increased			
subjects affected / exposed	21 / 542 (3.87%)	2 / 93 (2.15%)	15 / 540 (2.78%)
occurrences (all)	30	2	22
Blood Folate Decreased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Blood Glucose Fluctuation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Blood Lactate Dehydrogenase Increased			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	6 / 540 (1.11%)
occurrences (all)	7	0	7
Blood Magnesium Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Blood Magnesium Increased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Blood Parathyroid Hormone Increased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Blood Phosphorus Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Blood Thyroid Stimulating Hormone Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Blood Urea Increased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Blood Uric Acid Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Blood Uric Acid Increased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	2	0	9
Body Temperature Increased			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Brain Natriuretic Peptide Increased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Breath Sounds Abnormal			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	2	0	3
Carbon Dioxide Increased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cardiac Murmur			

subjects affected / exposed	8 / 542 (1.48%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	13	1	5
Electrocardiogram Abnormal			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Ejection Fraction Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Electrocardiogram Pr Prolongation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT Prolonged			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	11	0	4
Electrocardiogram St Segment Depression			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT Shortened			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Electrocardiogram T Wave Inversion			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	5	0	6
Glomerular Filtration Rate Decreased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Haematocrit Decreased			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	5	0	3
Heart Rate Increased			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Heart Rate Irregular			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	5	0	0
Hepatic Enzyme Increased			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Inspiratory Capacity Decreased			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
International Normalised Ratio Decreased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
International Normalised Ratio Increased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Intraocular Pressure Increased			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	1	1	2
Lasegue's Test Positive			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Lipase Increased			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	6
Liver Function Test Abnormal			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	5	0	0
Liver Palpable Subcostal			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Lymph Node Palpable			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Lymphocyte Count Decreased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	7	0	3
Lymphocyte Count Increased			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	2	0
Lymphocyte Percentage Decreased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	5	0	2
Neutrophil Count Decreased			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Neutrophil Count Increased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Neutrophil Percentage Decreased			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Oxygen Saturation Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Platelet Count Decreased			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	10	1	1
Platelet Count Increased			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	0	1	1
Prostatic Specific Antigen Increased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	0	0	3
Protein Total Increased			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Prothrombin Time Prolonged			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Prothrombin Time Shortened			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
QRS Axis Abnormal			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Red Blood Cell Count Decreased			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	5	0	1
Troponin I Increased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urinary Sediment Abnormal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urinary Sediment Present			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Urine Colour Abnormal			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Urine Output Increased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Vitamin B12 Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Vitamin D Decreased			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Waist Circumference Increased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	2	0	4
Weight Decreased			

subjects affected / exposed	42 / 542 (7.75%)	6 / 93 (6.45%)	27 / 540 (5.00%)
occurrences (all)	66	6	38
Weight Increased			
subjects affected / exposed	29 / 542 (5.35%)	2 / 93 (2.15%)	40 / 540 (7.41%)
occurrences (all)	43	2	48
White Blood Cell Count Decreased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	6	0	3
White Blood Cell Count Increased			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	0	2	3
Injury, poisoning and procedural complications			
Accident at Home			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Accidental Overdose			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Alcohol Poisoning			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Animal Bite			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Arthropod Bite			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	8	0	3
Arthropod Sting			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Back Injury			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	3	1	3
Bone Fragmentation			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cartilage Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cervical Vertebral Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Chest Injury			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Clavicle Fracture			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	3	1	0
Concussion			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Contrast Media Reaction			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences (all)	4	1	7
Contusion			
subjects affected / exposed	81 / 542 (14.94%)	6 / 93 (6.45%)	49 / 540 (9.07%)
occurrences (all)	116	10	72
Corneal Abrasion			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Cystitis Radiation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Device Breakage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Excoriation			
subjects affected / exposed	15 / 542 (2.77%)	2 / 93 (2.15%)	11 / 540 (2.04%)
occurrences (all)	20	3	12
Eye Injury			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Eye Penetration			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Face Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Facial Bones Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	47 / 542 (8.67%)	12 / 93 (12.90%)	20 / 540 (3.70%)
occurrences (all)	60	13	29
Fibula Fracture			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Foot Fracture			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	2	1	3
Foreign Body in Eye			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Fracture			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Gastroenteritis Radiation			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Hand Fracture			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	2	1	0
Head Injury			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Hip Fracture			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Humerus Fracture			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Iliotibial Band Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Incisional Hernia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Joint Dislocation			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Joint Injury			
subjects affected / exposed	7 / 542 (1.29%)	4 / 93 (4.30%)	3 / 540 (0.56%)
occurrences (all)	7	4	4
Joint Sprain			
subjects affected / exposed	12 / 542 (2.21%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	13	0	3
Laceration			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Ligament Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Ligament Rupture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Limb Injury			
subjects affected / exposed	8 / 542 (1.48%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	8	1	2
Lumbar Vertebral Fracture			

subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	2	1	0
Meniscus Lesion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Mouth Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Muscle Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Muscle Rupture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	3 / 540 (0.56%)
occurrences (all)	7	2	3
Neck Injury			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Open Wound			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	0	0	3
Patella Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pelvic Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Periorbital Haematoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Post Procedural Complication			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	3
Post Procedural Discharge			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Post Procedural Discomfort			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Post Procedural Haematuria			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Post-Traumatic Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Procedural Pain			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	11	0	7
Radiation Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Radiation Skin Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Radius Fracture			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Rib Fracture			
subjects affected / exposed	20 / 542 (3.69%)	2 / 93 (2.15%)	20 / 540 (3.70%)
occurrences (all)	26	3	24
Scapula Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Scratch			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Seroma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Skeletal Injury			

subjects affected / exposed	11 / 542 (2.03%)	2 / 93 (2.15%)	9 / 540 (1.67%)
occurrences (all)	12	2	9
Skin Injury			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Skin Laceration			
subjects affected / exposed	13 / 542 (2.40%)	6 / 93 (6.45%)	15 / 540 (2.78%)
occurrences (all)	24	10	21
Soft Tissue Injury			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Spinal Compression Fracture			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	5	1	3
Spinal Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Stent Occlusion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Stress Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Subdural Haematoma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Tendon Injury			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Tendon Rupture			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Thoracic Vertebral Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	4
Tibia Fracture			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Tooth Fracture			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	8	0	5
Traumatic Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Upper Limb Fracture			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	0	1	1
Wound			
subjects affected / exposed	11 / 542 (2.03%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	15	1	7
Wound Complication			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Wrist Fracture			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Phimosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	12 / 542 (2.21%)	0 / 93 (0.00%)	9 / 540 (1.67%)
occurrences (all)	12	0	11
Angina Unstable			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Aortic Valve Disease			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Aortic Valve Incompetence			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Arrhythmia			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	8	0	4
Arrhythmia Supraventricular			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Arteriosclerosis Coronary Artery			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Atrial Fibrillation			
subjects affected / exposed	24 / 542 (4.43%)	3 / 93 (3.23%)	22 / 540 (4.07%)
occurrences (all)	30	6	27
Atrial Flutter			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Atrial Tachycardia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Atrioventricular Block First Degree			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Bradycardia			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	5	0	4
Bundle Branch Block Left			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bundle Branch Block Right			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Cardiac Disorder			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cardiac Failure			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Cardiac Failure Acute			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cardiac Failure Congestive			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	7	0	1
Cardiac Flutter			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Cardiac Hypertrophy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cardiomegaly			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cardiovascular Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Chest Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Chest Pain			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Conduction Disorder			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Extrasystoles			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	3	0	4
Coronary Artery Disease			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Hypertrophic Cardiomyopathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Ischaemic Cardiomyopathy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Left Ventricular Dysfunction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Left Ventricular Hypertrophy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Mitral Valve Disease			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Mitral Valve Incompetence			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Myocardial Infarction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Myocardial Ischaemia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	6 / 540 (1.11%)
occurrences (all)	2	0	7
Palpitations			
subjects affected / exposed	14 / 542 (2.58%)	0 / 93 (0.00%)	9 / 540 (1.67%)
occurrences (all)	15	0	12
Right Ventricular Failure			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Sick Sinus Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Sinus Arrhythmia			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Sinus Bradycardia			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	5	0	3
Sinus Tachycardia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	2
Supraventricular Tachycardia			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	4	1	1
Tachyarrhythmia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	14 / 542 (2.58%)	2 / 93 (2.15%)	9 / 540 (1.67%)
occurrences (all)	15	2	11
Tricuspid Valve Incompetence			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Ventricular Extrasystoles			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	4	0	3
Wandering Pacemaker			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Nervous system disorders			
Akathisia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	2
Amnesia			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	7	1	3
Aphasia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	4

Aphonia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Ataxia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Balance Disorder			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	5	1	13
Bradykinesia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Brain Injury			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Burning Sensation			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	7	0	2
Carotid Arteriosclerosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Carpal Tunnel Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Cerebral Atrophy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cerebral Ischaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Cerebral Microangiopathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cerebrovascular Accident			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	0	0	3

Cluster Headache			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cognitive Disorder			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	7	1	4
Convulsion			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	2	3	1
Coordination Abnormal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Dementia Alzheimer's Type			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Diabetic Autonomic Neuropathy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Diabetic Neuropathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Disturbance in Attention			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Dizziness			
subjects affected / exposed	81 / 542 (14.94%)	7 / 93 (7.53%)	73 / 540 (13.52%)
occurrences (all)	116	9	95
Dizziness Postural			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	3	0	6
Drooling			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0

Dysarthria			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Dysgeusia			
subjects affected / exposed	19 / 542 (3.51%)	1 / 93 (1.08%)	15 / 540 (2.78%)
occurrences (all)	19	1	15
Dyskinesia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Dysphasia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Encephalopathy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Epidural Lipomatosis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Epiduritis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Epilepsy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Extrapyramidal Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Facial Neuralgia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Facial Paresis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Global Amnesia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Head Discomfort			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	1	1	0
Headache			
subjects affected / exposed	86 / 542 (15.87%)	9 / 93 (9.68%)	66 / 540 (12.22%)
occurrences (all)	129	9	87
Hydrocephalus			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	1	0	3
Hypoaesthesia			
subjects affected / exposed	18 / 542 (3.32%)	0 / 93 (0.00%)	12 / 540 (2.22%)
occurrences (all)	22	0	15
Hypoaesthesia Facial			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Hypogeusia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hypoglossal Nerve Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Hyposmia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Iiird Nerve Paralysis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Loss of Consciousness			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Memory Impairment			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	9 / 540 (1.67%)
occurrences (all)	7	1	9

Migraine			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	2
Migraine with Aura			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Monoplegia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Motor Dysfunction			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Myoclonus			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Nerve Compression			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	3 / 540 (0.56%)
occurrences (all)	8	3	3
Neuropathy Peripheral			
subjects affected / exposed	12 / 542 (2.21%)	7 / 93 (7.53%)	6 / 540 (1.11%)
occurrences (all)	23	7	6
Nystagmus			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	25 / 542 (4.61%)	1 / 93 (1.08%)	17 / 540 (3.15%)
occurrences (all)	33	2	18
Parkinson's Disease			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Parosmia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0

Peripheral Motor Neuropathy			
subjects affected / exposed	6 / 542 (1.11%)	2 / 93 (2.15%)	1 / 540 (0.19%)
occurrences (all)	8	2	1
Peripheral Sensory Neuropathy			
subjects affected / exposed	13 / 542 (2.40%)	0 / 93 (0.00%)	13 / 540 (2.41%)
occurrences (all)	24	0	17
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Polyneuropathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Poor Quality Sleep			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Post Herpetic Neuralgia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Presyncope			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Radiculopathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Reflexes Abnormal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Restless Legs Syndrome			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	4	2	1
Sciatica			
subjects affected / exposed	11 / 542 (2.03%)	1 / 93 (1.08%)	10 / 540 (1.85%)
occurrences (all)	13	2	14
Sensory Disturbance			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0

Sinus Headache			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	8	0	1
Somnolence			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences (all)	4	1	5
Speech Disorder Developmental			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Spinal Cord Compression			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	3	0	3
Syncope			
subjects affected / exposed	9 / 542 (1.66%)	3 / 93 (3.23%)	7 / 540 (1.30%)
occurrences (all)	9	3	7
Syncope Vasovagal			
subjects affected / exposed	5 / 542 (0.92%)	2 / 93 (2.15%)	2 / 540 (0.37%)
occurrences (all)	5	2	2
Transient Ischaemic Attack			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	10 / 542 (1.85%)	3 / 93 (3.23%)	6 / 540 (1.11%)
occurrences (all)	11	3	6
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	59 / 542 (10.89%)	12 / 93 (12.90%)	53 / 540 (9.81%)
occurrences (all)	112	17	84
Anaemia of Malignant Disease			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Disseminated Intravascular Coagulation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Haemorrhagic Anaemia			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Iron Deficiency Anaemia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Haemorrhagic Diathesis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Leukocytosis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Leukopenia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Lymphadenopathy			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	9	0	7
Lymphatic Obstruction			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	4 / 542 (0.74%)	3 / 93 (3.23%)	5 / 540 (0.93%)
occurrences (all)	4	3	9
Neutropenia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	5	0	5
Normochromic Normocytic Anaemia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Pernicious Anaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Splenic Granuloma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Thrombocythaemia			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	10 / 542 (1.85%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	26	0	13
Ear and labyrinth disorders			
Cerumen Impaction			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Conductive Deafness			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Deafness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Ear Congestion			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Ear Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Ear Pain			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	11	0	1
Eustachian Tube Dysfunction			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hearing Impaired			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Hyperacusis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hypoacusis			
subjects affected / exposed	11 / 542 (2.03%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	11	0	8

Middle Ear Effusion			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Tinnitus			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	8 / 540 (1.48%)
occurrences (all)	4	0	8
Tympanic Membrane Disorder			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Tympanic Membrane Perforation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Vertigo			
subjects affected / exposed	17 / 542 (3.14%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	22	1	5
Eye disorders			
Abnormal Sensation in Eye			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Asthenopia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Astigmatism			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Blepharitis			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	2	1	0
Blepharospasm			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Blindness Transient			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Blindness Unilateral			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Borderline Glaucoma			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cataract			
subjects affected / exposed	13 / 542 (2.40%)	4 / 93 (4.30%)	12 / 540 (2.22%)
occurrences (all)	18	5	14
Conjunctival Haemorrhage			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Conjunctivitis			
subjects affected / exposed	7 / 542 (1.29%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	8	1	3
Conjunctivitis Allergic			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Corneal Deposits			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Diplopia			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	7	0	3
Dry Eye			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	4	0	4
Episcleritis			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Erythema of Eyelid			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Exophthalmos			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Eye Discharge			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Eye Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Eye Haemorrhage			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	3	1	2
Eye Inflammation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Eye Pain			
subjects affected / exposed	3 / 542 (0.55%)	3 / 93 (3.23%)	3 / 540 (0.56%)
occurrences (all)	3	3	3
Eye Swelling			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Eyelid Irritation			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Eyelid Oedema			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Eyelid Ptosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Glaucoma			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Keratoconjunctivitis Sicca			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Lacrimation Increased			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	7	0	3
Macular Degeneration			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Mydriasis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Ocular Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Ocular Hyperaemia			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	4	1	6
Ocular Icterus			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Ocular Surface Disease			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Orbital Oedema			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Panophthalmitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Photopsia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Retinal Artery Occlusion			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Retinal Detachment			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Retinal Vein Thrombosis			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Vision Blurred			
subjects affected / exposed	11 / 542 (2.03%)	0 / 93 (0.00%)	9 / 540 (1.67%)
occurrences (all)	11	0	9
Visual Acuity Reduced			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	1	0	3
Visual Disturbance			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	4	0	4
Vitreous Floaters			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	12 / 542 (2.21%)	0 / 93 (0.00%)	9 / 540 (1.67%)
occurrences (all)	14	0	9
Abdominal Distension			
subjects affected / exposed	15 / 542 (2.77%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	15	1	12
Abdominal Hernia			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Abdominal Mass			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain			
subjects affected / exposed	49 / 542 (9.04%)	5 / 93 (5.38%)	44 / 540 (8.15%)
occurrences (all)	66	7	57
Abdominal Pain Lower			
subjects affected / exposed	13 / 542 (2.40%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	16	0	8
Abdominal Pain Upper			
subjects affected / exposed	19 / 542 (3.51%)	0 / 93 (0.00%)	20 / 540 (3.70%)
occurrences (all)	21	0	24

Abdominal Tenderness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Abdominal Wall Mass			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Anal Fistula			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Anal Haemorrhage			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Anal Pruritus			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Anorectal Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	2	0	3
Ascites			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Barrett's Oesophagus			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bowel Movement Irregularity			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Breath Odour			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Change of Bowel Habit			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	1	0	3

Colitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	4
Colitis Ischaemic			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Colonic Polyp			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	2	1	1
Constipation			
subjects affected / exposed	144 / 542 (26.57%)	15 / 93 (16.13%)	112 / 540 (20.74%)
occurrences (all)	204	16	140
Defaecation Urgency			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	7	0	1
Dental Caries			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	6	0	0
Dental Discomfort			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	135 / 542 (24.91%)	13 / 93 (13.98%)	98 / 540 (18.15%)
occurrences (all)	203	16	142
Diverticulum			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Diverticulum Intestinal			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	3	1	0
Dry Mouth			
subjects affected / exposed	20 / 542 (3.69%)	2 / 93 (2.15%)	16 / 540 (2.96%)
occurrences (all)	26	2	16
Duodenal Ulcer			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1

Dyspepsia			
subjects affected / exposed	62 / 542 (11.44%)	1 / 93 (1.08%)	28 / 540 (5.19%)
occurrences (all)	78	1	29
Dysphagia			
subjects affected / exposed	5 / 542 (0.92%)	2 / 93 (2.15%)	11 / 540 (2.04%)
occurrences (all)	5	2	14
Enteritis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Enterovesical Fistula			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Epigastric Discomfort			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	0	1	3
Eructation			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	3
Faecal Incontinence			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	2
Faeces Discoloured			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Flatulence			
subjects affected / exposed	23 / 542 (4.24%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	25	1	12
Food Poisoning			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	2	1	2
Frequent Bowel Movements			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Gastric Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Gastric Ulcer			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	8 / 542 (1.48%)	2 / 93 (2.15%)	5 / 540 (0.93%)
occurrences (all)	8	2	5
Gastritis Atrophic			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Gastritis Haemorrhagic			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal Angiodysplasia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Gastrointestinal Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal Motility Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Gastrooesophageal Reflux Disease			
subjects affected / exposed	27 / 542 (4.98%)	1 / 93 (1.08%)	24 / 540 (4.44%)
occurrences (all)	33	1	26
Gingival Pain			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	3	1	1
Gingivitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Haematemesis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	7 / 540 (1.30%)
occurrences (all)	9	2	7
Haemorrhoidal Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Haemorrhoids			
subjects affected / exposed	9 / 542 (1.66%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	12	1	7
Hiatus Hernia			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	2	1	1
Hypoaesthesia Oral			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Ileus			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Inflammatory Bowel Disease			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Inguinal Hernia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Intestinal Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Intra-Abdominal Haematoma			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Lip Dry			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Lip Swelling			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Lip Ulceration			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Loose Tooth			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Malocclusion			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Mesenteric Vein Thrombosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Mouth Ulceration			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	2
Nausea			
subjects affected / exposed	144 / 542 (26.57%)	15 / 93 (16.13%)	127 / 540 (23.52%)
occurrences (all)	210	17	155
Odynophagia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Oedema Mouth			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Oesophageal Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Oesophageal Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2

Oesophagitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Oral Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Oral Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Oral Pruritus			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Oroantral Fistula			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Painful Defaecation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pancreatic Cyst			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Pancreatic Insufficiency			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Paraesthesia Oral			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Peptic Ulcer			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Periodontal Disease			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Peritonitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Pigmentation Buccal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	7	0	2
Proctitis			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	1	1	1
Rectal Haemorrhage			
subjects affected / exposed	21 / 542 (3.87%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	24	1	12
Rectal Polyp			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Rectal Spasm			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Reflux Oesophagitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Retching			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Salivary Hypersecretion			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Sensitivity of Teeth			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Small Intestinal Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Stomach Discomfort			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	7	0	7

Stomatitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Tongue Black Hairy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Tongue Coated			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Tongue Ulceration			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Tooth Disorder			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	15 / 542 (2.77%)	2 / 93 (2.15%)	11 / 540 (2.04%)
occurrences (all)	18	2	13
Vomiting			
subjects affected / exposed	86 / 542 (15.87%)	12 / 93 (12.90%)	61 / 540 (11.30%)
occurrences (all)	115	14	76
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Hepatomegaly			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	0	1	1
Hepatotoxicity			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Hyperbilirubinaemia			
subjects affected / exposed	13 / 542 (2.40%)	1 / 93 (1.08%)	8 / 540 (1.48%)
occurrences (all)	26	1	13
Jaundice			

subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Jaundice Cholestatic			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Actinic Keratosis			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	10	0	12
Alopecia			
subjects affected / exposed	13 / 542 (2.40%)	2 / 93 (2.15%)	9 / 540 (1.67%)
occurrences (all)	14	2	9
Angioedema			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Blister			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Blood Blister			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Campbell De Morgan Spots			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cold Sweat			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Decubitus Ulcer			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	0	1	1
Dermal Cyst			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	6	0	1

Dermatitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	0	0	4
Dermatitis Acneiform			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Dermatitis Allergic			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Dermatitis Contact			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Dry Skin			
subjects affected / exposed	12 / 542 (2.21%)	4 / 93 (4.30%)	13 / 540 (2.41%)
occurrences (all)	13	4	18
Ecchymosis			
subjects affected / exposed	25 / 542 (4.61%)	1 / 93 (1.08%)	19 / 540 (3.52%)
occurrences (all)	32	1	26
Eczema			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	4	0	3
Erythema			
subjects affected / exposed	16 / 542 (2.95%)	2 / 93 (2.15%)	9 / 540 (1.67%)
occurrences (all)	17	3	9
Facial Wasting			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Haemorrhage Subcutaneous			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hair Growth Abnormal			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Hyperhidrosis			
subjects affected / exposed	20 / 542 (3.69%)	0 / 93 (0.00%)	21 / 540 (3.89%)
occurrences (all)	26	0	27

Hyperkeratosis			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	5	2	1
Hypertrichosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hypoaesthesia Facial			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Increased Tendency to Bruise			
subjects affected / exposed	22 / 542 (4.06%)	0 / 93 (0.00%)	14 / 540 (2.59%)
occurrences (all)	23	0	16
Ingrowing Nail			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Keloid Scar			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Lentigo			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Lipohypertrophy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Livedo Reticularis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Nail Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Neurodermatitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	2
Night Sweats			
subjects affected / exposed	13 / 542 (2.40%)	2 / 93 (2.15%)	10 / 540 (1.85%)
occurrences (all)	14	3	13

Onychalgia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Onychoclasis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Onychomadesis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Pain of Skin			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Palmar-Plantar Erythrodysaesthesia Syndrome			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	2
Periorbital Oedema			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	3
Petechiae			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	5	0	4
Photosensitivity Reaction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Pigmentation Disorder			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Pityriasis Rosea			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Precancerous Skin Lesion			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pruritus			

subjects affected / exposed	17 / 542 (3.14%)	0 / 93 (0.00%)	10 / 540 (1.85%)
occurrences (all)	19	0	11
Pruritus Generalised			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Psoriasis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Purpura			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	4 / 540 (0.74%)
occurrences (all)	6	1	5
Purpura Senile			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	49 / 542 (9.04%)	1 / 93 (1.08%)	21 / 540 (3.89%)
occurrences (all)	64	1	22
Rash Erythematous			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Rash Follicular			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Rash Macular			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Rash Maculo-Papular			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Rash Papular			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Rash Pruritic			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Rash Vesicular			

subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Rosacea			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	7	0	1
Scar			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	1	1	0
Seborrhoeic Dermatitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Skin Atrophy			
subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	9 / 540 (1.67%)
occurrences (all)	7	0	10
Skin Discolouration			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	6	0	2
Skin Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Skin Exfoliation			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Skin Fragility			
subjects affected / exposed	2 / 542 (0.37%)	2 / 93 (2.15%)	1 / 540 (0.19%)
occurrences (all)	2	2	1
Skin Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Skin Induration			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Skin Inflammation			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Skin Irritation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Skin Lesion			
subjects affected / exposed	15 / 542 (2.77%)	2 / 93 (2.15%)	5 / 540 (0.93%)
occurrences (all)	18	2	6
Skin Mass			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Skin Nodule			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Skin Striae			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Skin Toxicity			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Skin Ulcer			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	7	0	1
Stasis Dermatitis			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Swelling Face			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Telangiectasia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Urticaria			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	3	0	4
Renal and urinary disorders			

Anuria			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Azotaemia			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Bladder Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Bladder Disorder			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Bladder Obstruction			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bladder Hypertrophy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bladder Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bladder Stenosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bladder Spasm			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	4	1	1
Calculus Bladder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Calculus Ureteric			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Calculus Urethral			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1

Chromaturia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Cystitis Noninfective			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Enuresis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	3	0	3
Dysuria			
subjects affected / exposed	21 / 542 (3.87%)	1 / 93 (1.08%)	21 / 540 (3.89%)
occurrences (all)	26	1	26
Glycosuria			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	56 / 542 (10.33%)	4 / 93 (4.30%)	32 / 540 (5.93%)
occurrences (all)	89	4	40
Haemorrhage Urinary Tract			
subjects affected / exposed	11 / 542 (2.03%)	0 / 93 (0.00%)	6 / 540 (1.11%)
occurrences (all)	14	0	6
Hydronephrosis			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	15 / 540 (2.78%)
occurrences (all)	8	2	17
Hydroureter			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Kidney Enlargement			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Leukocyturia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Micturition Urgency			
subjects affected / exposed	11 / 542 (2.03%)	1 / 93 (1.08%)	12 / 540 (2.22%)
occurrences (all)	12	1	12

Nephrolithiasis			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	6	0	3
Nocturia			
subjects affected / exposed	38 / 542 (7.01%)	0 / 93 (0.00%)	29 / 540 (5.37%)
occurrences (all)	45	0	34
Obstructive Uropathy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Oliguria			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Pollakiuria			
subjects affected / exposed	56 / 542 (10.33%)	2 / 93 (2.15%)	55 / 540 (10.19%)
occurrences (all)	85	2	70
Polyuria			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	4	1	3
Proteinuria			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Pyelocaliectasis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Renal Colic			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Renal Failure			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	3	1	3
Renal Failure Acute			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	4	0	5
Renal Failure Chronic			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1

Renal Impairment			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	3
Renal Mass			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Renal Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Stress Urinary Incontinence			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	3	1	2
Ureteric Obstruction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	2	0	3
Ureteric Stenosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urethral Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urethral Obstruction			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Urethral Pain			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	6	1	5
Urethral Stenosis			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	4	0	0
Urge Incontinence			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urinary Bladder Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Urinary Hesitation			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	3	1	0
Urinary Incontinence			
subjects affected / exposed	37 / 542 (6.83%)	0 / 93 (0.00%)	25 / 540 (4.63%)
occurrences (all)	49	0	37
Urinary Retention			
subjects affected / exposed	18 / 542 (3.32%)	1 / 93 (1.08%)	14 / 540 (2.59%)
occurrences (all)	24	1	16
Urinary Tract Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Urinary Tract Inflammation			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urinary Tract Obstruction			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	8	0	1
Urinary Tract Pain			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urine Abnormality			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Urine Flow Decreased			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	8 / 540 (1.48%)
occurrences (all)	8	0	8
Urine Odour Abnormal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Urogenital Haemorrhage			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal Insufficiency			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Cushing's Syndrome			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Cushingoid			
subjects affected / exposed	7 / 542 (1.29%)	1 / 93 (1.08%)	12 / 540 (2.22%)
occurrences (all)	8	1	13
Feminisation Acquired			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Gynaecomastia			
subjects affected / exposed	14 / 542 (2.58%)	3 / 93 (3.23%)	21 / 540 (3.89%)
occurrences (all)	14	3	24
Hyperparathyroidism			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Hyperparathyroidism Primary			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Hypoparathyroidism			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Hypoparathyroidism Secondary			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Pituitary-Dependent Cushing's Syndrome			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Primary Hyperaldosteronism			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Steroid Withdrawal Syndrome			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Arthralgia			
subjects affected / exposed	172 / 542 (31.73%)	19 / 93 (20.43%)	131 / 540 (24.26%)
occurrences (all)	302	29	195
Arthritis			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	2
Arthropathy			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Back Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Back Pain			
subjects affected / exposed	199 / 542 (36.72%)	26 / 93 (27.96%)	180 / 540 (33.33%)
occurrences (all)	359	39	311
Bone Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Bone Pain			
subjects affected / exposed	144 / 542 (26.57%)	14 / 93 (15.05%)	112 / 540 (20.74%)
occurrences (all)	229	16	159
Bone Swelling			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bunion			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	4 / 542 (0.74%)	2 / 93 (2.15%)	7 / 540 (1.30%)
occurrences (all)	5	2	7
Coccydynia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	5 / 540 (0.93%)
occurrences (all)	2	0	5
Dupuytren's Contracture			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Exostosis			
subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	1	1	0
Flank Pain			
subjects affected / exposed	27 / 542 (4.98%)	1 / 93 (1.08%)	16 / 540 (2.96%)
occurrences (all)	30	1	21
Foot Deformity			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Groin Pain			
subjects affected / exposed	41 / 542 (7.56%)	0 / 93 (0.00%)	22 / 540 (4.07%)
occurrences (all)	52	0	33
Intervertebral Disc Compression			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Intervertebral Disc Protrusion			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Joint Range of Motion Decreased			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Joint Stiffness			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Joint Swelling			

subjects affected / exposed	7 / 542 (1.29%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	7	0	3
Limb Discomfort			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	7 / 540 (1.30%)
occurrences (all)	2	0	7
Low Turnover Osteopathy			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Lumbar Spinal Stenosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Mobility Decreased			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	6	0	1
Muscle Atrophy			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	5	0	2
Muscle Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Muscle Mass			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Muscle Spasms			
subjects affected / exposed	78 / 542 (14.39%)	2 / 93 (2.15%)	111 / 540 (20.56%)
occurrences (all)	107	2	173
Muscle Twitching			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	1	0	3
Muscular Weakness			
subjects affected / exposed	35 / 542 (6.46%)	5 / 93 (5.38%)	42 / 540 (7.78%)
occurrences (all)	55	6	52
Musculoskeletal Chest Pain			
subjects affected / exposed	22 / 542 (4.06%)	4 / 93 (4.30%)	26 / 540 (4.81%)
occurrences (all)	25	4	26
Musculoskeletal Discomfort			

subjects affected / exposed	12 / 542 (2.21%)	1 / 93 (1.08%)	13 / 540 (2.41%)
occurrences (all)	13	1	13
Musculoskeletal Disorder			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Musculoskeletal Pain			
subjects affected / exposed	97 / 542 (17.90%)	12 / 93 (12.90%)	77 / 540 (14.26%)
occurrences (all)	144	13	106
Musculoskeletal Stiffness			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	6 / 540 (1.11%)
occurrences (all)	11	0	6
Myalgia			
subjects affected / exposed	40 / 542 (7.38%)	3 / 93 (3.23%)	32 / 540 (5.93%)
occurrences (all)	48	3	39
Myopathy			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	2	2	8
Myopathy Steroid			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	2
Myosclerosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Myositis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Neck Mass			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Neck Pain			
subjects affected / exposed	30 / 542 (5.54%)	2 / 93 (2.15%)	17 / 540 (3.15%)
occurrences (all)	41	2	20
Nodule on Extremity			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Osteitis			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Osteoarthritis			
subjects affected / exposed	7 / 542 (1.29%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	10	1	6
Osteonecrosis			
subjects affected / exposed	8 / 542 (1.48%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	11	3	5
Osteopenia			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	5	0	4
Osteoporosis			
subjects affected / exposed	12 / 542 (2.21%)	3 / 93 (3.23%)	7 / 540 (1.30%)
occurrences (all)	13	4	7
Osteoporotic Fracture			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pain in Extremity			
subjects affected / exposed	107 / 542 (19.74%)	16 / 93 (17.20%)	89 / 540 (16.48%)
occurrences (all)	172	20	127
Pain in Jaw			
subjects affected / exposed	15 / 542 (2.77%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	23	1	7
Pathological Fracture			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Periarthritis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Polyarthritis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Pubic Pain			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Rotator Cuff Syndrome			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Sensation of Heaviness			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Soft Tissue Disorder			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Spinal Column Stenosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Spinal Osteoarthritis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Synovial Cyst			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	4	0	2
Tendon Pain			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Tendonitis			
subjects affected / exposed	1 / 542 (0.18%)	2 / 93 (2.15%)	2 / 540 (0.37%)
occurrences (all)	1	2	2
Torticollis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Trigger Finger			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Upper Extremity Mass			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Vertebral Column Mass			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			

Abdominal Abscess			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Abdominal Wall Abscess			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Abscess Jaw			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Abscess Limb			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	0	1	1
Abscess Oral			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Acute Sinusitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Anal Abscess			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Arthritis Bacterial			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Arthritis Infective			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bacterial Sepsis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bacteriuria			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	34 / 542 (6.27%)	0 / 93 (0.00%)	14 / 540 (2.59%)
occurrences (all)	39	0	16

Bronchitis Bacterial			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Bronchitis Viral			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Bronchopulmonary Aspergillosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Campylobacter Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Campylobacter Intestinal Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Candidiasis			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	6	0	3
Catheter Related Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Catheter Site Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	16 / 542 (2.95%)	4 / 93 (4.30%)	8 / 540 (1.48%)
occurrences (all)	18	7	8
Chest Wall Abscess			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Clostridial Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Clostridium Difficile Colitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1

Cystitis			
subjects affected / exposed	8 / 542 (1.48%)	2 / 93 (2.15%)	5 / 540 (0.93%)
occurrences (all)	12	2	6
Diverticulitis			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	9	0	4
Ear Infection			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	10	0	0
Endocarditis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Escherichia Urinary Tract Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
External Ear Cellulitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Eye Infection			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	5	1	2
Eyelid Infection			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Febrile Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	3
Folliculitis			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	5	0	4
Fungal Infection			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	4	0	3
Fungal Oesophagitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0

Fungal Skin Infection			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	2	0	3
Furuncle			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Gastroenteritis			
subjects affected / exposed	9 / 542 (1.66%)	1 / 93 (1.08%)	9 / 540 (1.67%)
occurrences (all)	9	1	9
Gastroenteritis Norovirus			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis Viral			
subjects affected / exposed	9 / 542 (1.66%)	3 / 93 (3.23%)	3 / 540 (0.56%)
occurrences (all)	9	4	3
Gastrointestinal Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Gingival Abscess			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Gingival Infection			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	3	0	2
Groin Abscess			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Hepatitis C			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Herpes Simplex			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Herpes Virus Infection			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0

Herpes Zoster			
subjects affected / exposed	10 / 542 (1.85%)	2 / 93 (2.15%)	8 / 540 (1.48%)
occurrences (all)	11	2	9
Hordeolum			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Infected Cyst			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Infected Skin Ulcer			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Influenza			
subjects affected / exposed	25 / 542 (4.61%)	3 / 93 (3.23%)	15 / 540 (2.78%)
occurrences (all)	35	3	16
Labyrinthitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Laryngitis			
subjects affected / exposed	4 / 542 (0.74%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	4	0	1
Lobar Pneumonia			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	3	0	1
Localised Infection			
subjects affected / exposed	5 / 542 (0.92%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	5	1	5
Lower Respiratory Tract Infection			
subjects affected / exposed	12 / 542 (2.21%)	5 / 93 (5.38%)	13 / 540 (2.41%)
occurrences (all)	17	8	16
Lower Respiratory Tract Infection Viral			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Lung Infection			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	3	0	3
Nail Infection			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	65 / 542 (11.99%)	5 / 93 (5.38%)	46 / 540 (8.52%)
occurrences (all)	94	8	59
Oesophageal Candidiasis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Oesophageal Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	8 / 542 (1.48%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	8	0	1
Oral Candidiasis			
subjects affected / exposed	12 / 542 (2.21%)	2 / 93 (2.15%)	10 / 540 (1.85%)
occurrences (all)	13	3	10
Oral Fungal Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Oral Herpes			
subjects affected / exposed	10 / 542 (1.85%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	13	1	5
Oral Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Osteomyelitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Otitis Externa			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Otitis Media			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Paronychia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Parotitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pertussis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	5	0	4
Pharyngitis Streptococcal			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	7	1	8
Pneumonia Klebsiella			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Postoperative Wound Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Prostatic Abscess			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Proteus Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Pyelonephritis			

subjects affected / exposed	1 / 542 (0.18%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	1	1	0
Rash Pustular			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	2
Respiratory Tract Infection			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	6	1	5
Rhinitis			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	2	1	3
Rotavirus Infection			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Salmonellosis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	3 / 542 (0.55%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	3	0	0
Septic Shock			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	29 / 542 (5.35%)	3 / 93 (3.23%)	5 / 540 (0.93%)
occurrences (all)	43	3	5
Skin Candida			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Skin Infection			
subjects affected / exposed	7 / 542 (1.29%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	8	1	1
Soft Tissue Infection			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Staphylococcal Infection			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Streptococcal Infection			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Subcutaneous Abscess			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Tinea Cruris			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Tinea Pedis			
subjects affected / exposed	5 / 542 (0.92%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	5	0	1
Tonsillitis			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Tooth Abscess			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	7 / 540 (1.30%)
occurrences (all)	4	1	8
Tooth Infection			
subjects affected / exposed	13 / 542 (2.40%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	15	1	4
Tracheitis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	74 / 542 (13.65%)	4 / 93 (4.30%)	43 / 540 (7.96%)
occurrences (all)	108	5	58
Urinary Tract Infection			
subjects affected / exposed	49 / 542 (9.04%)	11 / 93 (11.83%)	40 / 540 (7.41%)
occurrences (all)	73	21	61
Urinary Tract Infection Bacterial			

subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Urinary Tract Infection Pseudomonal			
subjects affected / exposed	0 / 542 (0.00%)	1 / 93 (1.08%)	0 / 540 (0.00%)
occurrences (all)	0	1	0
Urosepsis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	2
Viral Infection			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	2	0	4
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	8 / 542 (1.48%)	1 / 93 (1.08%)	1 / 540 (0.19%)
occurrences (all)	8	1	1
Wound Infection			
subjects affected / exposed	4 / 542 (0.74%)	1 / 93 (1.08%)	2 / 540 (0.37%)
occurrences (all)	4	1	2
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	56 / 542 (10.33%)	10 / 93 (10.75%)	40 / 540 (7.41%)
occurrences (all)	75	11	46
Central Obesity			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Decreased Appetite			
subjects affected / exposed	28 / 542 (5.17%)	0 / 93 (0.00%)	30 / 540 (5.56%)
occurrences (all)	31	0	31
Dehydration			
subjects affected / exposed	14 / 542 (2.58%)	4 / 93 (4.30%)	18 / 540 (3.33%)
occurrences (all)	17	5	20
Diabetes Mellitus			
subjects affected / exposed	12 / 542 (2.21%)	0 / 93 (0.00%)	8 / 540 (1.48%)
occurrences (all)	12	0	8
Diabetes Mellitus Inadequate Control			

subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Dyslipidaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Failure to Thrive			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	0	0	3
Fluid Retention			
subjects affected / exposed	6 / 542 (1.11%)	0 / 93 (0.00%)	3 / 540 (0.56%)
occurrences (all)	6	0	3
Glucose Tolerance Impaired			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Gout			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	1
Hyperalbuminaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	2 / 540 (0.37%)
occurrences (all)	1	0	2
Hypercalcaemia			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	6 / 540 (1.11%)
occurrences (all)	13	0	6
Hypercholesterolaemia			
subjects affected / exposed	20 / 542 (3.69%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	21	1	11
Hyperglycaemia			
subjects affected / exposed	52 / 542 (9.59%)	6 / 93 (6.45%)	41 / 540 (7.59%)
occurrences (all)	93	7	74
Hyperkalaemia			
subjects affected / exposed	12 / 542 (2.21%)	1 / 93 (1.08%)	11 / 540 (2.04%)
occurrences (all)	19	1	14
Hyperlipidaemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	1	0	1
Hypermagnesaemia			

subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	14	1	8
Hypernatraemia			
subjects affected / exposed	9 / 542 (1.66%)	0 / 93 (0.00%)	10 / 540 (1.85%)
occurrences (all)	20	0	14
Hyperphosphataemia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	2	0	2
Hypertriglyceridaemia			
subjects affected / exposed	8 / 542 (1.48%)	2 / 93 (2.15%)	5 / 540 (0.93%)
occurrences (all)	8	3	6
Hyperuricaemia			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	4	1	6
Hypoalbuminaemia			
subjects affected / exposed	5 / 542 (0.92%)	3 / 93 (3.23%)	5 / 540 (0.93%)
occurrences (all)	9	4	11
Hypocalcaemia			
subjects affected / exposed	8 / 542 (1.48%)	2 / 93 (2.15%)	2 / 540 (0.37%)
occurrences (all)	12	2	5
Hypoglycaemia			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	4 / 540 (0.74%)
occurrences (all)	2	0	5
Hypokalaemia			
subjects affected / exposed	99 / 542 (18.27%)	9 / 93 (9.68%)	68 / 540 (12.59%)
occurrences (all)	176	13	107
Hypomagnesaemia			
subjects affected / exposed	7 / 542 (1.29%)	2 / 93 (2.15%)	6 / 540 (1.11%)
occurrences (all)	8	2	6
Hyponatraemia			
subjects affected / exposed	14 / 542 (2.58%)	5 / 93 (5.38%)	15 / 540 (2.78%)
occurrences (all)	31	7	19
Hypophosphataemia			
subjects affected / exposed	11 / 542 (2.03%)	2 / 93 (2.15%)	8 / 540 (1.48%)
occurrences (all)	20	2	19
Hypovolaemia			

subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Increased Appetite			
subjects affected / exposed	10 / 542 (1.85%)	0 / 93 (0.00%)	11 / 540 (2.04%)
occurrences (all)	11	0	11
Malnutrition			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Metabolic Acidosis			
subjects affected / exposed	0 / 542 (0.00%)	0 / 93 (0.00%)	1 / 540 (0.19%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Tetany			
subjects affected / exposed	1 / 542 (0.18%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	1	0	0
Type 1 Diabetes Mellitus			
subjects affected / exposed	2 / 542 (0.37%)	0 / 93 (0.00%)	0 / 540 (0.00%)
occurrences (all)	2	0	0
Type 2 Diabetes Mellitus			
subjects affected / exposed	3 / 542 (0.55%)	1 / 93 (1.08%)	6 / 540 (1.11%)
occurrences (all)	3	1	6
Vitamin B12 Deficiency			
subjects affected / exposed	2 / 542 (0.37%)	1 / 93 (1.08%)	3 / 540 (0.56%)
occurrences (all)	2	1	3
Vitamin D Deficiency			
subjects affected / exposed	6 / 542 (1.11%)	1 / 93 (1.08%)	5 / 540 (0.93%)
occurrences (all)	6	1	5

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 April 2010	Expansion of genetic analyses to include biomarkers other than TMPRSS2-ERG
07 June 2011	Inclusion of an additional interim analysis of the Overall Survival (OS) co-primary endpoint, adjustment of the timing of the interim analyses for OS and addition of a strategy to adjust for a potential cross-over effect
02 April 2012	Updated the eligibility criteria and modified the schedule of events for subjects who will cross over from placebo to abiraterone acetate after the study drug assignments were unblinded, provided information on the IDMC recommendation to unblind the treatment assignments.
09 July 2012	The main reason of this amendment was to to allow subjects who had formerly received placebo treatment but had discontinued from the protocol and who met the eligibility criteria under Amendment 4, to also receive treatment with abiraterone acetate.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

These results are up to clinical cutoff (CCO) date (that is, 31 March 2014).

Notes: