Clinical trial results:
A Phase 4, Randomised, Double-Blind, Placebo-Controlled Study of Continued Enzalutamide Treatment Beyond Progression in Subjects With Chemotherapy-Naïve Metastatic Castration-Resistant Prostate Cancer (CRPC)

Summary

EudraCT number	2013-000722-54
Trial protocol	GB ES FI DE SK BE SE IT DK
Global end of trial date	31 August 2022

Results information

Result version number	v2 (current)
This version publication date	07 September 2023
First version publication date	30 October 2017
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	MDV3100-10

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01995513
WHO universal trial number (UTN)	-
Other trial identifiers	Alias Study Number: C3431013

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.govCall Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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 August 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the efficacy of combination treatment with continued enzalutamide plus abiraterone and prednisone (or prednisolone) compared with placebo plus abiraterone and prednisone as measured by progression free survival (PFS) after prostate specific antigen (PSA) progression on treatment with enzalutamide in subjects with chemotherapy-naïve metastatic castration-resistant prostate cancer (CRPC).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 234
Country: Number of subjects enrolled	United States: 16
Country: Number of subjects enrolled	Belgium: 16
Country: Number of subjects enrolled	Denmark: 39
Country: Number of subjects enrolled	Finland: 35
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Italy: 43
Country: Number of subjects enrolled	Slovakia: 16
Country: Number of subjects enrolled	Spain: 34
Country: Number of subjects enrolled	Sweden: 18
Country: Number of subjects enrolled	United Kingdom: 52
Worldwide total number of subjects	509
EEA total number of subjects	207

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)	95
From 65 to 84 years	385
85 years and over	29

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects received enzalutamide in first open label treatment period. Subjects in second open label treatment period could cross over to receive abiraterone and prednisone. In double blind period subjects were randomised to receive treatment with enzalutamide or placebo, each in combination with abiraterone and prednisone.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Enzalutamide 160 mg

Arm description:

Subjects who only received enzalutamide 160 mg as four 40 mg capsules, orally once daily until disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed-up until 30 days after last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received enzalutamide at a dose of 160 mg as four 40 mg capsules, once daily.

Arm title	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg

Arm description:

Subjects who received (after switching from enzalutamide), in second open label period, abiraterone 1000 mg as four 250 mg tablets, orally once daily and prednisone 10 mg administered as two 5 mg tablets, orally twice daily until disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed-up until 30 days after last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first.

Arm type	Experimental
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 at a dose of 5 mg twice daily.

Investigational medicinal product name	Abiraterone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet

Routes of administration	Oral use

Dosage and administration details:

Subjects received abiraterone at a dose of 1000 mg as four 250 mg tablets, once daily.

Arm title	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg

Arm description:

Subjects with confirmed prostate-specific antigen (PSA) progression at Week 21 in open label period, received enzalutamide 160 mg as four 40 mg capsules, orally once daily along with abiraterone 1000 mg as four 250-mg tablets, orally once daily and prednisone 5 mg tablet, orally twice daily in double blind treatment period, up to disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed up for 16 weeks at a 4-week interval after discontinuation of study drug for survival and subsequent antineoplastic therapy for prostate cancer.

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

Dosage and administration details:

Subjects received prednisone at a dose of 5 mg twice daily.

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

Dosage and administration details:

Subjects received abiraterone at a dose of 1000 mg as four 250 mg tablets, once daily.

Investigational medicinal product name	Enzalutamide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects received enzalutamide at a dose of 160 mg as four 40 mg capsules, once daily.

Arm title	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg

Arm description:

Subjects with confirmed PSA progression at Week 21 in open label period, received placebo matched to enzalutamide as four 40 mg capsules, orally once daily along with abiraterone 1000 mg as four 250-mg tablets, orally once daily and prednisone 5 mg tablet, orally twice daily in double blind treatment period, up to disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed up for 16 weeks at a 4-week interval after discontinuation of study drug for survival and subsequent antineoplastic therapy for prostate cancer.

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

Dosage and administration details:

Subjects received placebo matched to enzalutamide as four 40 mg capsules, once daily.

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

Dosage and administration details:

Subjects received abiraterone at a dose of 1000 mg as four 250 mg tablets, once 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 at a dose of 5 mg twice daily.

Number of subjects in period 1	Enzalutamide 160 mg	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg
Started	509	13	126
Treated	509	13	125
Completed	264	0	0
Not completed	245	13	126
Adverse event, serious fatal	14	-	-
Consent withdrawn by subject	20	-	5
Failure to Achieve PSA response at Week 13	43	-	-
Adverse event, non-fatal	40	-	14
Unspecified	34	2	3
Disease Progression	92	11	104
Protocol deviation	2	-	-

Number of subjects in period 1	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Started	125
Treated	124
Completed	0
Not completed	125
Adverse event, serious fatal	1
Consent withdrawn by subject	8
Failure to Achieve PSA response at Week 13	-
Adverse event, non-fatal	5
Unspecified	3

Disease Progression	107
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	509	509	
Age categorical Units: Subjects			
<65 years	95	95	
From 65-74 years	203	203	
75 years and over	211	211	
Age Continuous Units: years			
arithmetic mean	72.3		
standard deviation	± 8.31	-	
Sex: Female, Male Units:			
Female	0	0	
Male	509	509	

End points

End points reporting groups

Reporting group title	Enzalutamide 160 mg

Reporting group description:

Subjects who only received enzalutamide 160 mg as four 40 mg capsules, orally once daily until disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed-up until 30 days after last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first.

Reporting group title	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg

Reporting group description:

Subjects who received (after switching from enzalutamide), in second open label period, abiraterone 1000 mg as four 250 mg tablets, orally once daily and prednisone 10 mg administered as two 5 mg tablets, orally twice daily until disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed-up until 30 days after last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first.

Reporting group title	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg

Reporting group description:

Subjects with confirmed prostate-specific antigen (PSA) progression at Week 21 in open label period, received enzalutamide 160 mg as four 40 mg capsules, orally once daily along with abiraterone 1000 mg as four 250-mg tablets, orally once daily and prednisone 5 mg tablet, orally twice daily in double blind treatment period, up to disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed up for 16 weeks at a 4-week interval after discontinuation of study drug for survival and subsequent antineoplastic therapy for prostate cancer.

Reporting group title	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg

Reporting group description:

Subjects with confirmed PSA progression at Week 21 in open label period, received placebo matched to enzalutamide as four 40 mg capsules, orally once daily along with abiraterone 1000 mg as four 250-mg tablets, orally once daily and prednisone 5 mg tablet, orally twice daily in double blind treatment period, up to disease progression (as defined by radiographic imaging or unequivocal clinical progression or death on study), intolerable toxicity, or subject withdrawal, whichever occurred first. Subjects were followed up for 16 weeks at a 4-week interval after discontinuation of study drug for survival and subsequent antineoplastic therapy for prostate cancer.

Primary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)[1]

End point description:

Time from randomisation to 1st documentation of radiographic progression (RP),unequivocal clinical progression/death from any cause (death within 112 days of treatment discontinuation without evidence of RP),whichever occurred 1st per investigator. Unequivocal disease progression was pain requiring chronic administration of analgesics, decline of prostate cancer of Eastern Cooperative Oncology Group (ECOG) performance status score to 3/higher/initiation of new anticancer therapy/radiation therapy/surgical intervention due to tumor progression. ECOG score range= 0(no severity) to 5(maximum severity).RP for bone disease evaluated by appearance of 2/more new bone lesions per Prostate Cancer Clinical Trials Working Group 2 (PCWG2)/for soft tissue disease per Response Evaluation Criteria in Solid Tumor version 1.1. Subjects with no PFS at analysis date censored at last tumor assessment date prior to data cutoff date. ITT population included subjects randomly assigned to study treatment.

End point type	Primary

End point timeframe:

From randomisation until disease progression, last tumor assessment without disease progression or death due to any cause, whichever occurred first (maximum up to 20.3 months)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: months				
median (confidence interval 95%)	5.7 (4.6 to 8.1)	5.6 (4.5 to 7.3)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2176 [2]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.828
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.612
upper limit	1.119

Notes:

[2] - P-value was based on log-rank test stratified by PSA response (greater than or equal to [>=] 0 percent [%] to less than [<] 30% vs >=30%) at Week 13 in the open-label period.

Secondary: Time to Prostate Specific Antigen (PSA) Progression

End point title	Time to Prostate Specific Antigen (PSA) Progression[3]

End point description:

Time from date of randomisation to the date of first confirmed PSA progression as per Prostate Cancer Clinical Trials Working Group 2 (PCWG2). For subject's whose PSA decreased at Week 13 after randomisation, progression was defined as 25 percent (%) PSA increase relative to nadir or absolute increase of >=2 nanogram/milliliter (ng/mL) above nadir. Progression was confirmed if another assessment measured at least 3 weeks later met the criterion as well. For subject's whose PSA did not decrease at Week 13 after randomization, progression was defined as 25% PSA increase relative to baseline assessed 12 weeks after baseline. Subjects who were not known to have had a PFS event at the analysis date were censored at last PSA assessment date prior to data cutoff date. ITT population included all subjects randomly assigned to study treatment.

End point type	Secondary

End point timeframe:

From randomisation until disease progression, last tumor assessment without disease progression, whichever occurred first (maximum up to 11.1 months)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: months				
median (confidence interval 95%)	2.8 (2.8 to 2.9)	2.8 (2.8 to 2.8)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.45 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.874
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.617
upper limit	1.239

Notes:

[4] - P-value was based on log-rank test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Secondary: Prostate Specific Antigen (PSA) Response Rate

End point title	Prostate Specific Antigen (PSA) Response Rate[5]

End point description:

PSA response rate was defined as percentage of subjects with >=30% and >=50% decrease in PSA from baseline at randomisation to the maximal PSA response with a threshold of 30% and 50% respectively. PSA response was confirmed if another assessment measured at least 3 weeks later met the criterion as well. Evaluable ITT population included all subjects with a PSA value at baseline of Period 2 and at least 1 post baseline assessment. "n" = subjects evaluable for pre-specified rows.

End point type	Secondary

End point timeframe:

From randomisation until disease progression, last tumor assessment without disease progression, whichever occurred first (maximum up to 11.1 months)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	122		
Units: percentage of subjects				
number (confidence interval 95%)				
>= 50%	0.8 (0.0 to 4.4)	2.5 (0.5 to 7.0)		
>= 30%	2.4 (0.5 to 6.9)	2.5 (0.5 to 7.0)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo
Statistical analysis description:	
This analysis is reported for subjects with >=30% decrease from baseline in PSA response.	
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	246
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9917 [6]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rate
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.9
upper limit	3.82

Notes:

[6] - P-value was based on Cochran-Mantel-Haenszel mean score test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Statistical analysis title	Enzalutamide vs Placebo
Statistical analysis description:	
This analysis is reported for subjects with >=50% decrease from baseline in PSA response.	
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	246
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3101 [7]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rate
Point estimate	-1.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.82
upper limit	1.51

Notes:

[7] - P-value was based on Cochran-Mantel-Haenszel mean score test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)[8]

End point description:

Objective response rate as assessed by the investigator according to Response Evaluation Criteria in Solid Tumor version 1.1 (RECIST v1.1) was defined as 1) Percentage of subjects with confirmed best overall complete response (CR) and partial response (PR); 2) Percentage of subjects with CR, PR and stable disease (SD) for target lesions or non-progressive disease for non-target lesions. CR: Disappearance of all non-nodal target and non-target lesions, including target and non-target lymph nodes reduction to <10 millimeter (mm) in short axis. No new lesions and disappearance of all non-target lesions. PR: >= 30% decrease in sum of diameters of target lesions, compared to the sum at baseline. The short axis was used in the sum for target nodes, while the longest diameter was used in the sum for all other target lesions. ITT population (with measurable disease at screening) included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows.

End point type	Secondary

End point timeframe:

From randomisation until CR or PR, whichever occurred first (maximum up to 21.3 months)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	40		
Units: percentage of subjects				
number (confidence interval 95%)				
CR + PR	0.0 (0.00 to 9.25)	5.0 (0.61 to 16.92)		
CR + PR + SD	68.4 (51.35 to 82.50)	57.5 (40.89 to 72.96)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo

Statistical analysis description:

This analysis is reported for subjects with CR+PR.

Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg

Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1653 [9]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Objective Response Rate
Point estimate	-5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.75
upper limit	1.75

Notes:

[9] - P-value was based on Cochran-Mantel-Haenszel mean score test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Statistical analysis title	Enzalutamide vs Placebo

Statistical analysis description:

This analysis is reported for subjects with CR+PR+SD.

Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3216 [10]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Objective Response Rate
Point estimate	10.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.37
upper limit	32.21

Notes:

[10] - P-value was based on Cochran-Mantel-Haenszel mean score test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Secondary: Time to First Use of New Antineoplastic Therapy for Prostate Cancer

End point title	Time to First Use of New Antineoplastic Therapy for Prostate Cancer[11]

End point description:

It was defined as time from randomisation to the date of first use of subsequent antineoplastic therapy for prostate cancer. For subjects who had not started subsequent antineoplastic therapy as of data analysis cutoff date, the time to first use of subsequent antineoplastic therapy was censored at the date of last assessment. ITT population included all subjects randomly assigned to study treatment.

End point type	Secondary

End point timeframe:

From randomisation until date of first use of any antineoplastic therapy (after last dose date of Period 2, maximum up to 22.3 months

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: months				
median (confidence interval 95%)	10.3 (8.7 to 12.1)	8.6 (7.4 to 11.7)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3818 [12]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.861
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.616
upper limit	1.204

Notes:

[12] - P-value was based on log-rank test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Secondary: Rate of Pain Progression

End point title	Rate of Pain Progression[13]

End point description:

Rate of pain progression was defined percentage of subjects with an increase of >=30% from baseline in mean Brief Pain Inventory-Short Form (BPI-SF) pain intensity item scores of 4 items assessing average, worst, least, & intermediate pain severity. BPI-SF is an 11-item self-report questionnaire that is designed to assess the severity and impact of pain on daily functions of a subject. BPI-sf includes 4 questions that assess pain intensity (worst, least, average, right now) and 7 questions that assess impact of pain on daily functions (general activity, mood, walking ability, normal work, relations with other people, sleep, enjoyment of life). BPI-sf score range for each item was from 0=no pain to 10=worst possible pain. Total score was reported as average of individual questions ranges from 0 to 10, where lower scores indicated less pain/less pain interference. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows.

End point type	Secondary

End point timeframe:

Month 6

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	59		
Units: percentage of subjects				
number (confidence interval 95%)	36.2 (24.0 to 49.9)	27.1 (16.4 to 40.3)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2963 [14]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Progression Rate
Point estimate	9.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.69
upper limit	25.87

Notes:

[14] - P-value was based on Cochran-Mantel-Haenszel mean score test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period.

Secondary: Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Global Score

End point title	Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Global Score[15]

End point description:

The FACT-P is a multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain, as well as a global quality of life score which is the sum of all 5 domain scores and ranges from 0 to 156 where higher scores represent better quality of life. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows. "99999" = data not available as there were no subjects evaluable.

End point type	Secondary

End point timeframe:

Baseline, Week 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49, 53, 57, 61, 65, 69, 73, 77, 81, 85, 89

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n =125, 123)	116.4 (± 20.10)	119.0 (± 19.08)		
Change at Week 9 (n =102, 105)	-3.3 (± 14.90)	-2.2 (± 13.90)		
Change at Week 13 (n =88, 87)	-4.4 (± 14.44)	-0.5 (± 13.02)		
Change at Week 17 (n =83, 77)	-3.7 (± 12.40)	-2.3 (± 13.90)		
Change at Week 21 (n =69, 65)	-2.5 (± 12.33)	-2.7 (± 13.57)		
Change at Week 25 (n =61, 61)	-3.1 (± 13.47)	-2.1 (± 10.87)		
Change at Week 29 (n =51, 49)	-6.8 (± 13.98)	0.3 (± 12.10)		
Change at Week 33 (n =44, 43)	-5.9 (± 15.35)	-0.2 (± 12.90)		
Change at Week 37 (n =35, 33)	-6.1 (± 14.25)	0.9 (± 12.57)		
Change at Week 41 (n =31, 29)	-5.7 (± 12.17)	1.3 (± 14.13)		
Change at Week 45 (n =28, 26)	-6.0 (± 9.56)	-2.6 (± 16.27)		
Change at Week 49 (n =27, 18)	-4.2 (± 11.36)	1.8 (± 10.74)		
Change at Week 53 (n =20, 15)	-4.8 (± 10.17)	1.8 (± 14.68)		
Change at Week 57 (n =17, 13)	-4.3 (± 9.73)	0.1 (± 7.45)		
Change at Week 61 (n =13, 10)	-5.5 (± 10.63)	0.6 (± 12.94)		
Change at Week 65 (n =13, 7)	-7.0 (± 7.86)	1.9 (± 9.50)		
Change at Week 69 (n =10, 7)	-3.5 (± 11.37)	4.4 (± 13.29)		
Change at Week 73 (n =8, 1)	-0.7 (± 7.26)	-35.0 (± 99999)		
Change at Week 77 (n =7, 2)	-4.0 (± 9.81)	6.5 (± 30.41)		
Change at Week 81 (n =2, 0)	10.8 (± 9.24)	99999 (± 99999)		
Change at Week 85 (n =2, 0)	-5.5 (± 3.54)	99999 (± 99999)		
Change at Week 89 (n =1, 0)	-2.0 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Social/Family Well-Being Domain Scores

End point title	Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Social/Family Well-Being Domain Scores[16]

End point description:

The FACT-P is a multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain. Total subscale score range for social/family well-being domain is from 0 (worst response) to 32 (best response), where higher score indicate better quality of life. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows. "99999" = data not available as there

were no subjects evaluable.

End point type	Secondary

End point timeframe:

Baseline, Week 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49, 53, 57, 61, 65, 69, 73, 77, 81, 85, 89

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n =125, 123)	22.1 (± 5.80)	22.4 (± 4.84)		
Change at Week 9 (n =104, 108)	-0.5 (± 4.33)	-0.8 (± 4.13)		
Change at Week 13 (n =89, 89)	-0.4 (± 3.46)	-0.4 (± 3.86)		
Change at Week 17 (n =84, 80)	-0.1 (± 3.68)	-0.6 (± 4.64)		
Change at Week 21 (n =70, 67)	-0.5 (± 3.24)	-1.2 (± 5.75)		
Change at Week 25 (n =62, 62)	0.1 (± 2.79)	-1.0 (± 5.25)		
Change at Week 29 (n =51, 50)	-0.1 (± 3.20)	-0.2 (± 5.18)		
Change at Week 33 (n =44, 44)	-0.2 (± 3.21)	0.0 (± 4.95)		
Change at Week 37 (n =36, 33)	-0.8 (± 3.04)	0.8 (± 2.79)		
Change at Week 41 (n =31, 29)	-1.4 (± 3.75)	-0.1 (± 3.51)		
Change at Week 45 (n =28, 27)	-0.9 (± 3.36)	-0.8 (± 3.75)		
Change at Week 49 (n =27, 18)	-0.6 (± 2.88)	0.0 (± 2.65)		
Change at Week 53 (n =21, 15)	-1.0 (± 3.15)	0.4 (± 2.56)		
Change at Week 57 (n =17, 13)	-2.0 (± 3.06)	0.2 (± 1.29)		
Change at Week 61 (n =13, 10)	-1.5 (± 2.77)	-0.2 (± 1.80)		
Change at Week 65 (n =13, 7)	-1.5 (± 2.54)	-0.5 (± 0.96)		
Change at Week 69 (n =10, 7)	-1.4 (± 2.03)	-0.5 (± 0.96)		
Change at Week 73 (n =8, 1)	-0.6 (± 3.22)	-1.0 (± 99999)		
Change at Week 77 (n =7, 2)	-0.9 (± 3.41)	-0.5 (± 0.71)		
Change at Week 81 (n =2, 0)	6.2 (± 5.42)	99999 (± 99999)		
Change at Week 85 (n =2, 0)	-1.0 (± 1.41)	99999 (± 99999)		
Change at Week 89 (n =1, 0)	0.0 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Emotional Well-Being Domain Scores

End point title	Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Emotional Well-Being Domain Scores[17]

End point description:

The FACT-P is a multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain. Total subscale score range for emotional well-being domain is from 0 (worst response) to 24 (best response), where higher score indicate better quality of life. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows. "99999" = data not available as there were no subjects evaluable.

End point type	Secondary

End point timeframe:

Baseline, Week 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49, 53, 57, 61, 65, 69, 73, 77, 81, 85, 89

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n =126,124)	18.1 (± 3.80)	18.5 (± 4.06)		
Change at Week 9 (n =104, 107)	-0.1 (± 2.81)	0.1 (± 3.40)		
Change at Week 13 (n =91, 88)	-0.1 (± 3.55)	0.2 (± 3.09)		
Change at Week 17 (n =84, 79)	-0.2 (± 3.44)	0.4 (± 2.88)		
Change at Week 21 (n =71, 67)	0.3 (± 3.48)	0.1 (± 3.36)		
Change at Week 25 (n =62, 63)	0.3 (± 2.58)	0.3 (± 3.33)		
Change at Week 29 (n =51, 51)	-0.5 (± 3.56)	0.3 (± 3.27)		
Change at Week 33 (n =44, 45)	0.1 (± 3.33)	0.9 (± 2.99)		
Change at Week 37 (n =36, 34)	-0.7 (± 4.04)	0.9 (± 2.49)		
Change at Week 41 (n =31, 30)	0.1 (± 2.99)	1.4 (± 2.60)		
Change at Week 45 (n =28, 27)	-0.5 (± 3.23)	1.2 (± 2.76)		
Change at Week 49 (n =27, 19)	0.0 (± 3.00)	1.3 (± 2.75)		
Change at Week 53 (n =21, 16)	0.1 (± 2.72)	1.2 (± 3.23)		
Change at Week 57 (n =17, 14)	-0.4 (± 2.32)	1.6 (± 2.53)		
Change at Week 61 (n =13, 11)	-0.3 (± 3.14)	1.1 (± 3.62)		
Change at Week 65 (n =13, 7)	-0.9 (± 3.57)	2.9 (± 2.54)		
Change at Week 69 (n =10, 8)	-0.5 (± 2.93)	1.5 (± 2.93)		
Change at Week 73 (n =8, 2)	1.0 (± 2.83)	-5.0 (± 5.66)		
Change at Week 77 (n =7, 2)	0.1 (± 2.67)	2.0 (± 2.83)		
Change at Week 81 (n =2, 0)	1.5 (± 3.54)	99999 (± 99999)		
Change at Week 85 (n =2, 0)	-1.5 (± 0.71)	99999 (± 99999)		
Change at Week 89 (n =1, 0)	-3.0 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Functional Well-Being Domain Scores

End point title	Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Functional Well-Being Domain Scores[18]

End point description:

The FACT-P is a multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain. Total subscale score range for functional well-being domain is from 0 (worst response) to 28 (best response), where higher score indicate better quality of life. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows. "99999" = data not available as there were no subjects evaluable.

End point type	Secondary

End point timeframe:

Baseline, Week 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49, 53, 57, 61, 65, 69, 73, 77, 81, 85, 89

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n =126, 124)	20.2 (± 5.54)	20.3 (± 5.84)		
Change at Week 9 (n =104, 107)	-1.0 (± 4.23)	-0.7 (± 4.62)		
Change at Week 13 (n =91, 87)	-1.2 (± 4.07)	-0.4 (± 4.54)		
Change at Week 17 (n =84, 78)	-1.3 (± 4.00)	-0.5 (± 4.11)		
Change at Week 21 (n =71, 67)	-1.2 (± 5.03)	-0.7 (± 4.03)		
Change at Week 25 (n =62, 63)	-1.0 (± 3.41)	-0.3 (± 4.41)		
Change at Week 29 (n =51, 51)	-2.4 (± 4.67)	-0.2 (± 4.38)		
Change at Week 33 (n =44, 44)	-2.0 (± 5.14)	-0.7 (± 4.49)		
Change at Week 37 (n =36, 34)	-1.5 (± 5.22)	0.2 (± 5.72)		
Change at Week 41 (n =31, 30)	-2.1 (± 4.44)	0.8 (± 5.74)		
Change at Week 45 (n =28, 28)	-2.0 (± 3.37)	-0.3 (± 6.28)		
Change at Week 49 (n =27, 19)	-2.1 (± 4.55)	1.5 (± 5.02)		
Change at Week 53 (n =21, 16)	-1.6 (± 4.67)	1.3 (± 4.92)		

Change at Week 57 (n =17, 14)	-1.4 (± 4.06)	2.0 (± 4.37)		
Change at Week 61 (n =13, 11)	-0.8 (± 3.34)	2.9 (± 5.56)		
Change at Week 65 (n=13, 7)	-1.2 (± 2.21)	1.7 (± 2.75)		
Change at Week 69 (n =10, 8)	0.2 (± 1.48)	2.3 (± 4.23)		
Change at Week 73 (n =8, 2)	-0.6 (± 3.02)	4.0 (± 12.73)		
Change at Week 77 (n =7, 2)	-1.6 (± 3.91)	2.5 (± 9.19)		
Change at Week 81 (n =2, 0)	-1.5 (± 7.78)	99999 (± 99999)		
Change at Week 85 (n =2, 0)	-1.5 (± 2.12)	99999 (± 99999)		
Change at Week 89 (n =1, 0)	1.0 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Prostate Cancer Domain Scores

End point title	Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Prostate Cancer Domain Scores[19]

End point description:

The FACT-P is a multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain. Total subscale score range for prostate cancer domain is from 0 (worst response) to 48 (best response), where higher score indicated better quality of life with fewer symptoms. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows. "99999" = data not available as there were no subjects evaluable.

End point type	Secondary

End point timeframe:

Baseline, Week 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49, 53, 57, 61, 65, 69, 73, 77, 81, 85, 89

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n =126, 124)	33.2 (± 6.85)	34.2 (± 6.45)		
Change at Week 9 (n =104, 107)	-0.7 (± 5.97)	-0.9 (± 5.18)		
Change at Week 13 (n =90, 89)	-1.9 (± 5.91)	-0.1 (± 5.36)		
Change at Week 17 (n =84, 79)	-1.0 (± 5.36)	-1.4 (± 5.10)		
Change at Week 21 (n =71, 67)	-0.4 (± 5.13)	-0.6 (± 4.83)		
Change at Week 25 (n =61, 63)	-0.8 (± 6.93)	-0.8 (± 4.42)		

Change at Week 29 (n =52, 51)	-1.3 (± 5.75)	-0.3 (± 4.77)		
Change at Week 33 (n =44, 45)	-1.4 (± 5.16)	-0.6 (± 4.88)		
Change at Week 37 (n =35, 34)	-1.5 (± 4.88)	-0.8 (± 4.32)		
Change at Week 41 (n =31, 30)	-1.0 (± 5.13)	-0.7 (± 5.34)		
Change at Week 45 (n =28, 28)	-0.8 (± 4.88)	-1.7 (± 7.02)		
Change at Week 49 (n =27, 19)	-0.8 (± 4.26)	-0.9 (± 4.63)		
Change at Week 53 (n =20, 16)	-1.1 (± 3.65)	-1.8 (± 5.78)		
Change at Week 57 (n =17, 14)	-0.5 (± 3.67)	-3.3 (± 4.48)		
Change at Week 61 (n =13, 11)	-2.1 (± 4.29)	-3.1 (± 5.68)		
Change at Week 65 (n =13, 7)	-2.0 (± 4.05)	-2.6 (± 6.32)		
Change at Week 69 (n =10, 8)	-1.5 (± 3.30)	1.1 (± 5.79)		
Change at Week 73 (n =8, 2)	-0.2 (± 3.17)	-6.4 (± 9.32)		
Change at Week 77 (n =7, 2)	-1.0 (± 3.71)	-1.5 (± 13.44)		
Change at Week 81 (n =2, 0)	3.1 (± 1.22)	99999 (± 99999)		
Change at Week 85 (n =2, 0)	-0.5 (± 0.71)	99999 (± 99999)		
Change at Week 89 (n =1, 0)	0.0 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Physical Well-Being Domain Scores

End point title	Change From Baseline in Quality of Life as Assessed by Functional Assessment of Cancer Therapy-Prostate (FACT-P) Physical Well-Being Domain Scores[20]

End point description:

The FACT-P is a multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain. Total subscale score range for physical well-being domain is from 0 (worst response) to 28 (best response), where higher score indicate better quality of life. ITT population included all subjects randomly assigned to study treatment. "n" = subjects evaluable for pre-specified rows. "99999" = data not available as there were no subjects evaluable.

End point type	Secondary

End point timeframe:

Baseline, Week 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49, 53, 57, 61, 65, 69, 73, 77, 81, 85, 89

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: units on a scale				
arithmetic mean (standard deviation)				
Baseline (n =126,124)	22.9 (± 4.50)	23.6 (± 4.42)		
Change at Week 9 (n =105, 109)	-0.8 (± 4.04)	0.1 (± 3.20)		
Change at Week 13 (n =91, 89)	-1.0 (± 4.11)	0.0 (± 2.63)		
Change at Week 17 (n =85, 80)	-1.1 (± 3.26)	-0.3 (± 2.97)		
Change at Week 21 (n =70, 68)	-0.8 (± 3.11)	-0.8 (± 4.48)		
Change at Week 25 (n =62, 63)	-1.7 (± 4.23)	-0.4 (± 2.90)		
Change at Week 29 (n =51, 51)	-2.5 (± 4.89)	0.3 (± 2.67)		
Change at Week 33 (n =44, 45)	-2.5 (± 5.37)	0.1 (± 3.18)		
Change at Week 37 (n =36, 34)	-1.8 (± 4.50)	0.4 (± 3.13)		
Change at Week 41 (n =31, 30)	-1.5 (± 3.94)	2.12 (± 2.80)		
Change at Week 45 (n =28, 28)	-2.0 (± 3.72)	-0.4 (± 3.59)		
Change at Week 49 (n =27, 19)	-0.9 (± 3.78)	0.6 (± 2.12)		
Change at Week 53 (n =21, 16)	-0.2 (± 3.78)	0.7 (± 2.85)		
Change at Week 57 (n =17, 14)	-0.4 (± 3.25)	0.4 (± 2.37)		
Change at Week 61 (n =13, 11)	-0.8 (± 3.11)	0.4 (± 2.32)		
Change at Week 65 (n =13, 7)	-1.9 (± 4.25)	0.4 (± 1.99)		
Change at Week 69 (n =10, 8)	-0.3 (± 4.08)	-0.5 (± 2.67)		
Change at Week 73 (n =8, 2)	-0.3 (± 2.05)	-3.0 (± 5.66)		
Change at Week 77 (n =7, 2)	-0.7 (± 2.81)	4.0 (± 4.24)		
Change at Week 81 (n =2, 0)	1.5 (± 2.12)	99999 (± 99999)		
Change at Week 85 (n =2, 0)	-1.0 (± 0.0)	99999 (± 99999)		
Change at Week 89 (n =1, 0)	0.0 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Degradation of the Functional Assessment of Cancer Therapy-Prostate (FACT-P) Global Score

End point title	Time to Degradation of the Functional Assessment of Cancer Therapy-Prostate (FACT-P) Global Score[21]

End point description:

Time to degradation of FACT-P was defined as time from randomisation to first assessment with at least a 10-point decrease from baseline in global FACT-P score for each subject. The FACT-P is multidimensional, self-reported quality of life instrument consisting of 27 core items that assess subject function in 4 domains: physical, social/family, emotional, and functional well-being, and supplemented by 12 site-specific items to assess for prostate-related symptoms. Each item is rated on a 0 to 4 Likert-type scale, and then combined to produce subscale scores for each domain, as well as global quality of life score which is sum of all 5 domain scores and ranges from 0 to 156 with higher scores representing better quality of life. Subjects with no score degradation at time of analysis data cutoff were censored at date of last assessment showing no degradation. Evaluable ITT population included all subjects with PSA value at baseline of Period 2 and at least 1 post baseline assessment.

End point type	Secondary

End point timeframe:

From randomisation up to maximum of 18.4 months

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint is reporting statistics for the arms specified.

End point values	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	125		
Units: months				
median (confidence interval 95%)	4.6 (3.7 to 6.5)	6.4 (5.5 to 13.9)		

Statistical analyses

Statistical analysis title	Enzalutamide vs Placebo
Comparison groups	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg v Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Number of subjects included in analysis	251
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0739 [22]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.399
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.967
upper limit	2.025

Notes:

[22] - P-value was based on log-rank test stratified by PSA response (>=0% to <30% vs >=30%) at Week 13 in the open-label period

Other pre-specified: Percentage of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Percentage of Subjects With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point description:

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

End point type	Other pre-specified

End point timeframe:

Baseline up to 30 days after the last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first (maximum of 99.4 months)

End point values	Enzalutamide 160 mg	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	509	13	125	124
Units: percentage of subjects				
number (not applicable)				
TEAEs	93.5	100	91.2	92.7
SAEs	32.0	30.8	37.6	29.8

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Adverse Events (AEs) Leading to Study Drug Discontinuation

End point title	Percentage of Subjects With Adverse Events (AEs) Leading to Study Drug Discontinuation

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Outcome of an AE was response to a question answered by the investigator: 'Is the AE leading to study discontinuation or death?' as 'yes'. Safety population included all subjects who received any amount of study drug. "99999" signifies data was not available because no subjects were evaluable.

End point type	Other pre-specified

End point timeframe:

Baseline up to 30 days after the last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first (maximum of 99.4 months)

End point values	Enzalutamide 160 mg	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	509	13	125	124
Units: percentage of subjects				
number (not applicable)				
Discontinuation with Enza/Placebo(n=509,0,125,124)	11.8	99999	23.2	11.3

Discontinuation with Abiraterone (n=0,13,125,124)	99999	7.7	23.2	12.9
Discontinuation with Prednisone (n=0,13,125,124)	99999	7.7	16.0	12.1

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Adverse Events (AEs) Leading to Death

End point title	Percentage of Subjects With Adverse Events (AEs) Leading to Death

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Outcome of an AE was response to a question answered by the investigator: 'Is the AE leading to study discontinuation or death?' as 'yes'. Safety population analysed. Here number of subjects analysed is the subjects evaluable for this endpoint.

End point type	Other pre-specified

End point timeframe:

Baseline up to 30 days after the last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first (maximum of 99.4 months)

End point values	Enzalutamide 160 mg	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	509	13	125	124
Units: percentage of subjects				
number (not applicable)	5.9	0	3.2	2.4

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Treatment-Emergent Treatment-Related Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point title	Percentage of Subjects With Treatment-Emergent Treatment-Related Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point description:

Treatment-related AE was any untoward medical occurrence attributed to study drug in a subject who received study drug. 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 first dose 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. Relatedness to

study drug was assessed by the investigator. Safety population included all subjects who received any amount of study drug.

End point type	Other pre-specified

End point timeframe:

Baseline up to 30 days after the last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first (maximum of 99.4 months)

End point values	Enzalutamide 160 mg	Enza 160 mg crossing to Abiraterone 1000 mg+ Prednisone 10 mg	Enza 160 mg+ Abiraterone 1000 mg+ Prednisone 10mg	Placebo + Abiraterone 1000 mg+ Prednisone 10 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	509	13	125	124
Units: percentage of subjects				
number (not applicable)				
TEAEs related to Enza/Placebo (n=509, 0, 125, 124)	66.6	99999	46.4	36.3
TEAEs related to Abiraterone (n=0, 13, 125, 124)	99999	38.5	54.4	45.2
TEAEs related to Prednisone (n=0, 13, 125, 124)	99999	7.7	36.0	32.3
SAEs related to Enza/Placebo (n= 509, 0, 125, 124)	4.1	99999	7.2	4.8
SAEs related to Abiraterone (n=0, 13, 125, 124)	99999	0	7.2	4.0
SAEs related to Prednisone (n=0, 13, 125, 124)	99999	0	2.4	4.8

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Baseline up to 30 days after the last dose of study drug or before initiation of a new antitumor treatment, whichever occurred first (maximum duration of exposure: 99.4 months)

Adverse event reporting additional description:

Events may appear as both an AE and SAE. However, distinct events are presented. An event may be categorised as serious in one subject and non-serious in another, or a subject may have experienced both a serious and non-serious event. Safety population analysed for deaths due to AEs and ITT population analysed for total number of deaths.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.1

Reporting groups

Reporting group title	Enzalutamide 160 mg

Reporting group description:

Subjects who only received enzalutamide 160 mg as four 40 mg capsules, orally once daily in the study.

Reporting group title	Placebo + Abiraterone 1000 mg + Prednisone 10mg

Reporting group description:

Subjects who received placebo matched to enzalutamide as four 40 mg capsules, orally once daily along with abiraterone 1000 mg as four 250-mg tablets, orally once daily and prednisone 5 mg tablet, orally twice daily in the study.

Reporting group title	Enzalutamide 160mg+Abiraterone 1000mg+ Prednisone 10mg

Reporting group description:

Subjects who received enzalutamide 160 mg as four 40 mg capsules, orally once daily along with abiraterone 1000 mg as four 250-mg tablets, orally once daily and prednisone 5 mg tablet, orally twice daily in the study.

Reporting group title	Enzalutamide crossing over to Abiraterone + Prednisone

Reporting group description:

Subjects who received (after switching from enzalutamide) abiraterone 1000 mg as four 250 mg tablets, orally once daily and prednisone 10 mg administered as two 5 mg tablets, orally twice daily in the study.

Serious adverse events	Enzalutamide 160 mg	Placebo + Abiraterone 1000 mg + Prednisone 10mg	Enzalutamide 160mg+Abiraterone 1000mg+ Prednisone 10mg
Total subjects affected by serious adverse events			
subjects affected / exposed	163 / 509 (32.02%)	37 / 124 (29.84%)	47 / 125 (37.60%)
number of deaths (all causes)	32	10	14
number of deaths resulting from adverse events	30	3	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 myelomonocytic leukaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Malignant pleural effusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung squamous cell carcinoma stage 0			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Renal cell carcinoma			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Prostate cancer metastatic			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Neuroendocrine carcinoma metastatic			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Metastasis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (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
Metastases to liver			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Metastatic pain			
subjects affected / exposed	3 / 509 (0.59%)	2 / 124 (1.61%)	3 / 125 (2.40%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma metastatic			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Ureteral neoplasm			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Second primary malignancy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial rupture			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Hypovolaemic shock			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	1 / 4	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	7 / 509 (1.38%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 2
deaths causally related to treatment / all	6 / 6	1 / 1	2 / 2
Fatigue			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (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
Malaise			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Oedema peripheral			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Pain			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Local swelling			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Balanitis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
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			
Pneumothorax			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	4 / 509 (0.79%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Haemothorax			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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			
Depression			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Acetabulum fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Burns third degree			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis radiation			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (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
Fall			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	1 / 8	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femur fracture			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (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
Hip fracture			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal injury			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Radius fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Spinal fracture			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	2 / 2	0 / 0	0 / 0
Angina unstable			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 5	0 / 0	1 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Coronary artery disease			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Coronary artery stenosis			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	2 / 509 (0.39%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	2 / 2	1 / 1	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Mitral valve disease			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Aortic valve stenosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal arrhythmia			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Brain oedema			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Dysarthria			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Cerebrovascular accident			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Nerve root compression			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Unresponsive to stimuli			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stupor			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
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	5 / 509 (0.98%)	2 / 124 (1.61%)	5 / 125 (4.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Cerebellar syndrome			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Lethargy			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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 positional			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (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
Eye disorders			

Exophthalmos			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 disorders			
Abdominal pain			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (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
Colonic fistula			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 ulcer			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 perforation			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Nausea			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (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
Rectal polyp			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Gastrointestinal toxicity			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 chronic			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic lesion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus bladder			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (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
Obstructive uropathy			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	2 / 509 (0.39%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction			

subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	3 / 509 (0.59%)	2 / 124 (1.61%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	11 / 509 (2.16%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences causally related to treatment / all	0 / 14	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urethral			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (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
Nephrolithiasis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			

subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Mobility decreased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 509 (0.00%)	2 / 124 (1.61%)	0 / 125 (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
Osteonecrosis of jaw			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Osteoporosis			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Osteoporotic fracture			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 5	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
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			
Abscess jaw			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Cellulitis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (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
Enterococcal sepsis			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis tuberculous			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	7 / 509 (1.38%)	3 / 124 (2.42%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 7	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
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	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (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
Septic shock			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			

subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
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 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dystrophic calcification			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Hypercalcaemia			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Malnutrition			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Enzalutamide crossing over to Abiraterone + Prednisone		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 13 (30.77%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic myelomonocytic leukaemia			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cancer pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to bone				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant pleural effusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm progression				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung squamous cell carcinoma stage 0				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lentigo maligna				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal squamous cell carcinoma				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
B-cell lymphoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer metastatic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma metastatic				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to spine				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to liver				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma metastatic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureteral neoplasm				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Second primary malignancy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangiocarcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatocellular carcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm progression				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Aortic stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arterial rupture				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphoedema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Circulatory collapse				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disease progression			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multi-organ failure			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Local swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Balanitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumothorax			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemothorax				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary mass				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Confusional state			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test abnormal			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Acetabulum fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns third degree				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical vertebral fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis radiation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Femur fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular pseudoaneurysm				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laceration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute coronary syndrome				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina unstable				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sick sinus syndrome				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mitral valve disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nodal arrhythmia				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar infarction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysarthria			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dementia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cognitive disorder			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nerve root compression				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Unresponsive to stimuli				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stupor				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal cord compression				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dementia Alzheimer's type			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lethargy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			

Exophthalmos				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic fistula				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer haemorrhage				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal perforation				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal polyp				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal haematoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal perforation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal toxicity				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct obstruction				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis chronic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic lesion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice cholestatic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Calculus bladder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive uropathy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prerenal failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure acute				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureteric obstruction				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary incontinence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus urethral				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus ureteric				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract obstruction				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephropathy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Mobility decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical spinal stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chondrocalcinosis pyrophosphate				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthralgia				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis of jaw				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoporosis				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoporotic fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess jaw				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal sepsis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis tuberculous				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ophthalmic herpes zoster				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection enterococcal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metapneumovirus infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dystrophic calcification				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gout			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Enzalutamide 160 mg	Placebo + Abiraterone 1000 mg + Prednisone 10mg	Enzalutamide 160mg+Abiraterone 1000mg+ Prednisone 10mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	474 / 509 (93.12%)	113 / 124 (91.13%)	113 / 125 (90.40%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign urinary tract neoplasm			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Bowen's disease			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Cancer pain			

subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Choroidal haemangioma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Fibroma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Metastases to central nervous system			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Renal neoplasm			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic keratosis			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Skin cancer			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Skin papilloma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
Squamous cell carcinoma of skin			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	8	0	0
Tumour pain			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Basal cell carcinoma			
subjects affected / exposed	12 / 509 (2.36%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	22	1	6

Adenoma benign			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Malignant melanoma in situ			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Meningioma			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Myelodysplastic syndrome			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Ureteral neoplasm			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Keratoacanthoma			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Vascular disorders			
Flushing			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Aortic aneurysm			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Deep vein thrombosis			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	3	1	1
Haematoma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Hot flush			
subjects affected / exposed	90 / 509 (17.68%)	3 / 124 (2.42%)	8 / 125 (6.40%)
occurrences (all)	102	3	9
Hypotension			

subjects affected / exposed	9 / 509 (1.77%)	4 / 124 (3.23%)	0 / 125 (0.00%)
occurrences (all)	9	4	0
Lymphoedema			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Orthostatic hypotension			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	2
Peripheral coldness			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Phlebitis superficial			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	52 / 509 (10.22%)	11 / 124 (8.87%)	24 / 125 (19.20%)
occurrences (all)	69	13	38
Haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Surgical and medical procedures			
Cataract operation			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Dupuytren's contracture operation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Endodontic procedure			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Glaucoma surgery			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Mole excision			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Nasal polypectomy			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Peripheral nerve decompression			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Pterygium operation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Skin neoplasm excision			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Tendon sheath incision			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Tooth extraction			
subjects affected / exposed	3 / 509 (0.59%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	4	4	0
Hip surgery			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	5	2	1
Abasia			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	26 / 509 (5.11%)	3 / 124 (2.42%)	5 / 125 (4.00%)
occurrences (all)	43	4	5
Catheter site haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	3 / 509 (0.59%)	4 / 124 (3.23%)	5 / 125 (4.00%)
occurrences (all)	3	4	5
Chest discomfort			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	4	0	2
Cyst			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Infusion site extravasation			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Device occlusion			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Dysplasia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
Facial pain			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	206 / 509 (40.47%)	19 / 124 (15.32%)	20 / 125 (16.00%)
occurrences (all)	305	26	28
Feeling abnormal			

subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Feeling drunk			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Feeling hot			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	8 / 509 (1.57%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	8	2	1
General physical health deterioration			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Hunger			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Hyperpyrexia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypothermia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Inflammation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	9 / 509 (1.77%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	15	1	1
Device failure			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	5	1	0
Injection site swelling			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Local swelling			

subjects affected / exposed	7 / 509 (1.38%)	0 / 124 (0.00%)	6 / 125 (4.80%)
occurrences (all)	7	0	7
Malaise			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	3 / 125 (2.40%)
occurrences (all)	5	0	3
Medical device complication			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	8	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	7 / 509 (1.38%)	2 / 124 (1.61%)	4 / 125 (3.20%)
occurrences (all)	8	3	5
Oedema			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	3 / 125 (2.40%)
occurrences (all)	7	0	3
Oedema peripheral			
subjects affected / exposed	51 / 509 (10.02%)	18 / 124 (14.52%)	8 / 125 (6.40%)
occurrences (all)	56	20	9
Pain			
subjects affected / exposed	8 / 509 (1.57%)	2 / 124 (1.61%)	6 / 125 (4.80%)
occurrences (all)	9	2	6
Performance status decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	11 / 509 (2.16%)	3 / 124 (2.42%)	3 / 125 (2.40%)
occurrences (all)	13	4	3
Irritability			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Device leakage			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Axillary pain			

subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Discomfort			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Suprapubic pain			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	5	1	0
Milk allergy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Contrast media allergy			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
Drug hypersensitivity			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Hypersensitivity			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Social circumstances			
Physical assault			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Balanitis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Breast pain			

subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Breast tenderness			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Genital rash			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gynaecomastia			
subjects affected / exposed	11 / 509 (2.16%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	12	1	0
Pelvic pain			
subjects affected / exposed	10 / 509 (1.96%)	4 / 124 (3.23%)	2 / 125 (1.60%)
occurrences (all)	10	4	2
Perineal pain			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Prostatic pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Prostatitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pruritus genital			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Scrotal pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Balanoposthitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Testicular pain			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Respiratory, thoracic and mediastinal			

disorders			
Allergic sinusitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Acute respiratory failure			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Alveolitis			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Atelectasis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	4	1	1
Dysphonia			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Dyspnoea			
subjects affected / exposed	40 / 509 (7.86%)	5 / 124 (4.03%)	6 / 125 (4.80%)
occurrences (all)	48	8	6
Dyspnoea exertional			
subjects affected / exposed	9 / 509 (1.77%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	10	0	1
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Emphysema			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Epistaxis			

subjects affected / exposed	10 / 509 (1.96%)	2 / 124 (1.61%)	3 / 125 (2.40%)
occurrences (all)	11	3	3
Haemoptysis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Interstitial lung disease			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Laryngeal disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Laryngeal erythema			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Laryngeal oedema			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lung infiltration			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Nasal obstruction			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Oropharyngeal pain			
subjects affected / exposed	8 / 509 (1.57%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	8	1	1
Cough			
subjects affected / exposed	30 / 509 (5.89%)	9 / 124 (7.26%)	7 / 125 (5.60%)
occurrences (all)	34	9	7
Pleuritic pain			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	5	1	0
Pulmonary embolism			
subjects affected / exposed	3 / 509 (0.59%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	3	2	0
Pulmonary fibrosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pulmonary mass			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Rales			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Respiration abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Respiratory failure			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Rhinorrhoea			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	3	0	2
Rhonchi			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sinus disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sleep apnoea syndrome			

subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Sneezing			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Wheezing			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Pneumonia aspiration			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Bronchial obstruction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	7 / 509 (1.38%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	11	1	0
Anxiety			
subjects affected / exposed	16 / 509 (3.14%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	17	2	1
Apathy			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Bruxism			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	10 / 509 (1.96%)	1 / 124 (0.81%)	4 / 125 (3.20%)
occurrences (all)	12	1	4

Delirium			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	3	1	1
Depressed mood			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Depression			
subjects affected / exposed	12 / 509 (2.36%)	5 / 124 (4.03%)	1 / 125 (0.80%)
occurrences (all)	12	6	1
Disorientation			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Emotional disorder			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Agitation			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Flat affect			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	40 / 509 (7.86%)	6 / 124 (4.84%)	6 / 125 (4.80%)
occurrences (all)	44	7	6
Mood altered			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Mood swings			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Nightmare			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0

Sleep disorder			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Stress			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Hallucination			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Daydreaming			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Restlessness			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Cholelithiasis			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Hepatic lesion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hepatic steatosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hepatotoxicity			
subjects affected / exposed	0 / 509 (0.00%)	2 / 124 (1.61%)	2 / 125 (1.60%)
occurrences (all)	0	4	4
Hypertransaminasaemia			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	0	6	1
Jaundice			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Non-alcoholic steatohepatitis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Pneumobilia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Biliary colic			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Hepatic function abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood calcium decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Blood cholesterol increased			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 509 (0.39%)	6 / 124 (4.84%)	8 / 125 (6.40%)
occurrences (all)	3	10	14
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 509 (0.20%)	2 / 124 (1.61%)	4 / 125 (3.20%)
occurrences (all)	1	2	6
Bacterial test positive			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Blood albumin increased			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	6	2	1
Blood calcium increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	7	1	1
Blood iron decreased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Blood potassium decreased			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Blood potassium increased			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	2	1	3
Blood pressure orthostatic decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Blood urine present			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Cardiac murmur			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Cardioactive drug level increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Cystoscopy			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Ejection fraction decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed	6 / 509 (1.18%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	9	2	0
Blood creatinine increased			
subjects affected / exposed	8 / 509 (1.57%)	2 / 124 (1.61%)	3 / 125 (2.40%)
occurrences (all)	9	2	3

Heart rate irregular			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
International normalised ratio increased			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Liver function test abnormal			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	1	1	5
Lymph node palpable			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Norovirus test positive			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
Troponin increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Urine output decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Vitamin B12 decreased			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
Weight decreased			
subjects affected / exposed	25 / 509 (4.91%)	4 / 124 (3.23%)	3 / 125 (2.40%)
occurrences (all)	33	4	4
Weight increased			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	3	2	1
White blood cell count decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
White blood cell count increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Heart sounds abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Haematocrit decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Accidental overdose			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Ankle fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Bone contusion			

subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Chest injury			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	8 / 509 (1.57%)	3 / 124 (2.42%)	2 / 125 (1.60%)
occurrences (all)	11	3	2
Limb injury			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Eye contusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Face injury			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	51 / 509 (10.02%)	10 / 124 (8.06%)	14 / 125 (11.20%)
occurrences (all)	85	11	18
Femur fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Foreign body in eye			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Fractured coccyx			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis radiation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hand fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Head injury			

subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Humerus fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Injection related reaction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Laceration			
subjects affected / exposed	9 / 509 (1.77%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	11	1	3
Ligament sprain			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Excoriation			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	2 / 125 (1.60%)
occurrences (all)	5	3	2
Lumbar vertebral fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Spinal compression fracture			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	3	1	1
Muscle injury			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	12	0	0
Overdose			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Pelvic fracture			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Periorbital contusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Post procedural haematuria			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Post-traumatic pain			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Procedural hypotension			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Procedural nausea			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Procedural pain			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Procedural vomiting			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Radius fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Rib fracture			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	8	1	1
Skeletal injury			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	1	1	1
Skin wound			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Multiple injuries			

subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Thoracic vertebral fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Toxicity to various agents			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Traumatic fracture			
subjects affected / exposed	0 / 509 (0.00%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	0	2	1
Urethral injury			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	4	1	9
Wound dehiscence			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Wound secretion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Wrist fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Clavicle fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Incision site hypoaesthesia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lower limb fracture			

subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Scapula fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Tendon rupture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Forearm fracture			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Bundle branch block right			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	1	1	1
Cardiac failure			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Cardiac failure congestive			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Chordae tendinae rupture			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Coronary artery stenosis			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Diastolic dysfunction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Extrasystoles			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	4	1	0
Left ventricular dysfunction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	8 / 509 (1.57%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	8	1	0
Atrial flutter			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Atrial fibrillation			
subjects affected / exposed	5 / 509 (0.98%)	4 / 124 (3.23%)	3 / 125 (2.40%)
occurrences (all)	5	4	3
Mitral valve disease			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Aortic valve stenosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Angina pectoris			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	4	0	1
Arrhythmia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Palpitations			

subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	2	1	1
Myocardial ischaemia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Myocardial infarction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Mitral valve prolapse			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Right ventricular dysfunction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Ventricular extrasystoles			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Tachycardia			
subjects affected / exposed	7 / 509 (1.38%)	3 / 124 (2.42%)	0 / 125 (0.00%)
occurrences (all)	8	3	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Angina unstable			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block second degree			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Mitral valve incompetence			

subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Nervous system disorders			
Balance disorder			
subjects affected / exposed	8 / 509 (1.57%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	8	0	1
Ageusia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Amnesia			
subjects affected / exposed	9 / 509 (1.77%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	9	0	0
Ataxia			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Burning sensation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypoglossal nerve paralysis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Cauda equina syndrome			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Cognitive disorder			
subjects affected / exposed	11 / 509 (2.16%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	19	0	3
Dementia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Dementia Alzheimer's type			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Disturbance in attention			
subjects affected / exposed	7 / 509 (1.38%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	8	1	1

Dizziness			
subjects affected / exposed	49 / 509 (9.63%)	5 / 124 (4.03%)	6 / 125 (4.80%)
occurrences (all)	58	6	6
Dizziness postural			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Dysarthria			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Dysgeusia			
subjects affected / exposed	24 / 509 (4.72%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	26	1	4
Dyskinesia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Head discomfort			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	50 / 509 (9.82%)	3 / 124 (2.42%)	6 / 125 (4.80%)
occurrences (all)	55	4	6
Hemiparesis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hyperreflexia			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	12 / 509 (2.36%)	3 / 124 (2.42%)	5 / 125 (4.00%)
occurrences (all)	12	3	5
Carpal tunnel syndrome			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Hypokinesia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	10 / 509 (1.96%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	10	1	0
Loss of consciousness			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Memory impairment			
subjects affected / exposed	16 / 509 (3.14%)	2 / 124 (1.61%)	3 / 125 (2.40%)
occurrences (all)	20	2	3
Migraine			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Nerve compression			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	6	1	0
Neuropathy peripheral			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Paraesthesia			
subjects affected / exposed	23 / 509 (4.52%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	25	0	1
Parkinsonian gait			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Parkinson's disease			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Parosmia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1

Peripheral sensory neuropathy			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Poor quality sleep			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Post herpetic neuralgia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Presyncope			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	5	1	1
Radicular pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	37 / 509 (7.27%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	40	1	5
Trigeminal neuralgia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	7	2	0
Somnolence			
subjects affected / exposed	7 / 509 (1.38%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	7	1	1
Syncope			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	6	0	0
Tension headache			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Tongue paralysis			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0

Transient ischaemic attack			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Tremor			
subjects affected / exposed	5 / 509 (0.98%)	3 / 124 (2.42%)	1 / 125 (0.80%)
occurrences (all)	5	3	1
Cerebellar atrophy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Cerebral atrophy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Facial paresis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sensory disturbance			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
VIIth nerve paralysis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	2
Visual field defect			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Pancytopenia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Leukocytosis			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	32 / 509 (6.29%)	8 / 124 (6.45%)	5 / 125 (4.00%)
occurrences (all)	41	11	10
Bone marrow failure			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Haemorrhagic anaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	4	3	0
Pernicious anaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Motion sickness			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Hearing impaired			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Deafness neurosensory			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Deafness bilateral			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Cerumen impaction			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Vertigo			
subjects affected / exposed	14 / 509 (2.75%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	20	1	0
Vertigo positional			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Ear pain			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Eye disorders			
Eye irritation			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Eye inflammation			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Eye disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Exophthalmos			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Dry eye			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	5	0	1
Diplopia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	10 / 509 (1.96%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	11	1	2
Conjunctival haemorrhage			

subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Cataract			
subjects affected / exposed	13 / 509 (2.55%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	21	2	2
Amaurosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Macular fibrosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Night blindness			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Ocular icterus			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Retinal artery occlusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Strabismus			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Trichiasis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Vision blurred			

subjects affected / exposed	3 / 509 (0.59%)	3 / 124 (2.42%)	0 / 125 (0.00%)
occurrences (all)	3	4	0
Visual acuity reduced			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Vitreous floaters			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Eyelid margin crusting			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Glaucoma			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Iritis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Eye swelling			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Vitreous haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Anal haemorrhage			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	4	0	1
Diarrhoea			
subjects affected / exposed	73 / 509 (14.34%)	15 / 124 (12.10%)	9 / 125 (7.20%)
occurrences (all)	88	16	11

Abdominal pain lower			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	4	1	3
Abdominal pain			
subjects affected / exposed	16 / 509 (3.14%)	8 / 124 (6.45%)	7 / 125 (5.60%)
occurrences (all)	16	8	8
Abdominal distension			
subjects affected / exposed	8 / 509 (1.57%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	9	0	0
Abdominal discomfort			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	7	0	0
Apical granuloma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Barrett's oesophagus			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Breath odour			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Cheilitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Colitis microscopic			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	84 / 509 (16.50%)	14 / 124 (11.29%)	22 / 125 (17.60%)
occurrences (all)	97	15	27
Dental caries			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Abdominal pain upper			
subjects affected / exposed	21 / 509 (4.13%)	4 / 124 (3.23%)	0 / 125 (0.00%)
occurrences (all)	23	4	0

Faecal incontinence			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Eructation			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Erosive oesophagitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	3	1	2
Dyspepsia			
subjects affected / exposed	16 / 509 (3.14%)	4 / 124 (3.23%)	5 / 125 (4.00%)
occurrences (all)	19	4	6
Dry mouth			
subjects affected / exposed	4 / 509 (0.79%)	2 / 124 (1.61%)	2 / 125 (1.60%)
occurrences (all)	4	2	2
Diverticulum intestinal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Faecaloma			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	13 / 509 (2.55%)	5 / 124 (4.03%)	4 / 125 (3.20%)
occurrences (all)	14	5	4
Gastritis			
subjects affected / exposed	1 / 509 (0.20%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	1	2	0
Gastric ulcer			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0

Gastric mucosa erythema			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Frequent bowel movements			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Food poisoning			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	12 / 509 (2.36%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	12	1	3
Faeces hard			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gingival bleeding			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Oesophageal pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Haematochezia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Haemorrhoids			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	4	1	0
Hiatus hernia			
subjects affected / exposed	2 / 509 (0.39%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	2	2	0
Inguinal hernia			
subjects affected / exposed	3 / 509 (0.59%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	3	2	0

Odynophagia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Nausea			
subjects affected / exposed	100 / 509 (19.65%)	12 / 124 (9.68%)	23 / 125 (18.40%)
occurrences (all)	127	12	33
Mouth ulceration			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Melaena			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Localised intraabdominal fluid collection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lip oedema			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Lip dry			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Large intestine polyp			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Gingival inflammation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Pancreatitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Paraesthesia oral			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Periodontal disease			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Rectal haemorrhage			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	3	0	2
Retching			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Tongue disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	12 / 509 (2.36%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	14	1	0
Umbilical hernia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	29 / 509 (5.70%)	2 / 124 (1.61%)	11 / 125 (8.80%)
occurrences (all)	34	3	14
Pancreatic disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sensitivity of teeth			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Anal fissure			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Crohn's disease			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Diverticulum			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lip swelling			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Oral discharge			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Oral mucosal blistering			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	11 / 509 (2.16%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	11	0	0
Actinic keratosis			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	7	0	1
Actinic prurigo			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Blister			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Cold sweat			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Cutaneous lupus erythematosus			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Decubitus ulcer			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Dermal cyst			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Dermatitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Dermatitis contact			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Diabetic foot			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	5	2	0
Eczema			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Granuloma annulare			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Haemorrhage subcutaneous			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Hair growth abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	11 / 509 (2.16%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	11	1	1
Hypertrichosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Intertrigo			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Miliaria			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	3	1	1
Panniculitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pain of skin			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Photodermatosis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	8 / 509 (1.57%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	11	0	0

Psoriasis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	17 / 509 (3.34%)	4 / 124 (3.23%)	8 / 125 (6.40%)
occurrences (all)	25	4	9
Rash erythematous			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Rash maculo-papular			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Rash papular			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Skin exfoliation			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	8	1	1
Nail disorder			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Onychoclasis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Penile ulceration			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	2	0	2
Swelling face			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Sticky skin			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Nail growth abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Solar lentigo			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Skin atrophy			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Incontinence			
subjects affected / exposed	7 / 509 (1.38%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	8	1	2
Bladder dysfunction			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Bladder pain			

subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Bladder spasm			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Calculus bladder			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	4	0	1
Calculus ureteric			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	12 / 509 (2.36%)	5 / 124 (4.03%)	1 / 125 (0.80%)
occurrences (all)	13	5	1
Haematuria			
subjects affected / exposed	20 / 509 (3.93%)	11 / 124 (8.87%)	6 / 125 (4.80%)
occurrences (all)	34	14	6
Haemorrhage urinary tract			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Hydronephrosis			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	4	1	3
Lower urinary tract symptoms			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Urinary hesitation			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Nephrolithiasis			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Nocturia			
subjects affected / exposed	18 / 509 (3.54%)	5 / 124 (4.03%)	1 / 125 (0.80%)
occurrences (all)	18	5	1
Pollakiuria			

subjects affected / exposed	13 / 509 (2.55%)	4 / 124 (3.23%)	3 / 125 (2.40%)
occurrences (all)	14	4	3
Polyuria			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Prerenal failure			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Renal colic			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Renal impairment			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Strangury			
subjects affected / exposed	1 / 509 (0.20%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	1	2	1
Ureteric obstruction			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Urethral dilatation			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Urethral pain			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	1	0	2
Urethral stenosis			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Urethritis noninfective			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Urge incontinence			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Micturition urgency			
subjects affected / exposed	7 / 509 (1.38%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	7	0	0
Urinary incontinence			
subjects affected / exposed	18 / 509 (3.54%)	2 / 124 (1.61%)	3 / 125 (2.40%)
occurrences (all)	18	2	3
Urinary retention			
subjects affected / exposed	8 / 509 (1.57%)	2 / 124 (1.61%)	2 / 125 (1.60%)
occurrences (all)	9	2	2
Urinary tract obstruction			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Urine odour abnormal			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Cushingoid			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	0	1	1
Goitre			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Thyroid mass			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0

Cushing's syndrome			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Coccydynia			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Arthralgia			
subjects affected / exposed	78 / 509 (15.32%)	16 / 124 (12.90%)	22 / 125 (17.60%)
occurrences (all)	99	20	34
Arthritis			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Arthropathy			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	112 / 509 (22.00%)	28 / 124 (22.58%)	26 / 125 (20.80%)
occurrences (all)	150	34	34
Bone fistula			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	21 / 509 (4.13%)	4 / 124 (3.23%)	3 / 125 (2.40%)
occurrences (all)	25	6	4
Bursitis			
subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	4	1	1
Muscle atrophy			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Mobility decreased			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Joint swelling			

subjects affected / exposed	4 / 509 (0.79%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	4	1	3
Joint stiffness			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Joint range of motion decreased			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Inguinal mass			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	14 / 509 (2.75%)	5 / 124 (4.03%)	1 / 125 (0.80%)
occurrences (all)	14	5	2
Flank pain			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	7	0	2
Muscle fatigue			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Myopathy			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	24 / 509 (4.72%)	3 / 124 (2.42%)	2 / 125 (1.60%)
occurrences (all)	26	3	2
Musculoskeletal stiffness			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	3 / 125 (2.40%)
occurrences (all)	4	0	3
Musculoskeletal pain			
subjects affected / exposed	38 / 509 (7.47%)	9 / 124 (7.26%)	13 / 125 (10.40%)
occurrences (all)	42	11	16
Musculoskeletal discomfort			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Musculoskeletal chest pain			
subjects affected / exposed	27 / 509 (5.30%)	7 / 124 (5.65%)	14 / 125 (11.20%)
occurrences (all)	31	9	19
Muscular weakness			
subjects affected / exposed	21 / 509 (4.13%)	6 / 124 (4.84%)	6 / 125 (4.80%)
occurrences (all)	26	9	6
Muscle tightness			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Muscle spasms			
subjects affected / exposed	10 / 509 (1.96%)	9 / 124 (7.26%)	4 / 125 (3.20%)
occurrences (all)	12	11	9
Myositis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Osteoarthritis			
subjects affected / exposed	7 / 509 (1.38%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	9	1	0
Osteonecrosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Osteonecrosis of jaw			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Osteopenia			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Osteoporosis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	2	0	2
Pain in extremity			

subjects affected / exposed	37 / 509 (7.27%)	7 / 124 (5.65%)	12 / 125 (9.60%)
occurrences (all)	45	9	15
Synovitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Synovial cyst			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	6	1	0
Spinal osteoarthritis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Spinal column stenosis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Scoliosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Plantar fasciitis			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Pathological fracture			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Pain in jaw			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	25 / 509 (4.91%)	4 / 124 (3.23%)	2 / 125 (1.60%)
occurrences (all)	28	4	3
Trismus			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Tendon disorder			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Dupuytren's contracture			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Foot deformity			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Limb discomfort			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Spinal deformity			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Tendon calcification			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Abscess neck			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Atypical mycobacterial infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	7	2	1
Bronchopneumonia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Abdominal abscess			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Carbuncle			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	2
Catheter site infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	3	1	0
Conjunctivitis infective			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	5	3	1
Diverticulitis			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Ear infection			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	3	1	2
Erysipelas			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Eyelid infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Folliculitis			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Fungal skin infection			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	2	0	2
Furuncle			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	6 / 509 (1.18%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	7	0	1
Genital candidiasis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gingival infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 509 (0.00%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	0	2	0
Helicobacter infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Mediastinitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	5 / 125 (4.00%)
occurrences (all)	5	2	5
Herpes zoster oticus			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Infected cyst			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1

Infected dermal cyst			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	2 / 509 (0.39%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	2	1	0
Infection parasitic			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	24 / 509 (4.72%)	5 / 124 (4.03%)	8 / 125 (6.40%)
occurrences (all)	28	5	8
Injection site infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Labyrinthitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Lobar pneumonia			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Lower respiratory tract infection			
subjects affected / exposed	20 / 509 (3.93%)	4 / 124 (3.23%)	2 / 125 (1.60%)
occurrences (all)	24	5	2
Lung infection			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1

Herpes simplex			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Skin candida			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	2 / 125 (1.60%)
occurrences (all)	3	1	2
Oral candidiasis			
subjects affected / exposed	9 / 509 (1.77%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	9	1	1
Oral herpes			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Otitis media			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Peritonitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Pneumonia			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	4	0	2
Pulpitis dental			
subjects affected / exposed	0 / 509 (0.00%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0

Respiratory tract infection			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	5	1	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	5	0	0
Scrotal abscess			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sialoadenitis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	5 / 509 (0.98%)	3 / 124 (2.42%)	0 / 125 (0.00%)
occurrences (all)	7	3	0
Nasopharyngitis			
subjects affected / exposed	36 / 509 (7.07%)	8 / 124 (6.45%)	0 / 125 (0.00%)
occurrences (all)	55	10	0
Tooth abscess			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
Tinea cruris			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Tracheitis			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	30 / 509 (5.89%)	5 / 124 (4.03%)	9 / 125 (7.20%)
occurrences (all)	32	5	12
Urethritis			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0

Urinary tract infection			
subjects affected / exposed	34 / 509 (6.68%)	7 / 124 (5.65%)	10 / 125 (8.00%)
occurrences (all)	56	7	12
Urosepsis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	3 / 509 (0.59%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	5	1	2
Skin infection			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Soft tissue infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Tooth infection			
subjects affected / exposed	5 / 509 (0.98%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	5	2	0
Arthritis infective			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Corona virus infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	1	0	1
Gastric infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Oral fungal infection			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Staphylococcal skin infection			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Abnormal loss of weight			

subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	7 / 509 (1.38%)	7 / 124 (5.65%)	11 / 125 (8.80%)
occurrences (all)	8	11	13
Hypomagnesaemia			
subjects affected / exposed	4 / 509 (0.79%)	2 / 124 (1.61%)	1 / 125 (0.80%)
occurrences (all)	5	2	3
Decreased appetite			
subjects affected / exposed	83 / 509 (16.31%)	11 / 124 (8.87%)	14 / 125 (11.20%)
occurrences (all)	99	11	16
Dehydration			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	5	1	3
Diabetes mellitus			
subjects affected / exposed	1 / 509 (0.20%)	2 / 124 (1.61%)	0 / 125 (0.00%)
occurrences (all)	1	2	0
Dyslipidaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Fluid overload			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	2 / 125 (1.60%)
occurrences (all)	0	0	2
Gout			
subjects affected / exposed	1 / 509 (0.20%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	1	1	0
Hypercalcaemia			
subjects affected / exposed	5 / 509 (0.98%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	5	1	0
Hypercholesterolaemia			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Hyperglycaemia			

subjects affected / exposed	10 / 509 (1.96%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences (all)	10	1	2
Hyperkalaemia			
subjects affected / exposed	5 / 509 (0.98%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	7	0	0
Hyperlipidaemia			
subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	2	0	0
Hypernatraemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	6 / 509 (1.18%)	1 / 124 (0.81%)	3 / 125 (2.40%)
occurrences (all)	6	1	3
Hypoglycaemia			
subjects affected / exposed	2 / 509 (0.39%)	3 / 124 (2.42%)	1 / 125 (0.80%)
occurrences (all)	2	4	1
Vitamin D deficiency			
subjects affected / exposed	4 / 509 (0.79%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	4	0	0
Vitamin B complex deficiency			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Malnutrition			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	3	0	0
Lactic acidosis			
subjects affected / exposed	1 / 509 (0.20%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			

subjects affected / exposed	2 / 509 (0.39%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	2	0	1
Increased appetite			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	6 / 509 (1.18%)	1 / 124 (0.81%)	0 / 125 (0.00%)
occurrences (all)	7	5	0
Vitamin B12 deficiency			
subjects affected / exposed	3 / 509 (0.59%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	3	0	1
Folate deficiency			
subjects affected / exposed	0 / 509 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences (all)	0	0	1

Non-serious adverse events	Enzalutamide crossing over to Abiraterone + Prednisone		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign urinary tract neoplasm			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bowen's disease			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cancer pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Choroidal haemangioma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Fibroma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metastases to central nervous			

system				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Renal neoplasm				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Seborrhoeic keratosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin cancer				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin papilloma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Squamous cell carcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tumour pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Basal cell carcinoma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Adenoma benign				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Malignant melanoma in situ				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Meningioma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Myelodysplastic syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ureteral neoplasm			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Keratoacanthoma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Aortic aneurysm			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Peripheral artery thrombosis			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Peripheral coldness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Phlebitis superficial			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Cataract operation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dupuytren's contracture operation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Endodontic procedure			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Glaucoma surgery			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Mole excision			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Nasal polypectomy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Peripheral nerve decompression subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Pterygium operation subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Skin neoplasm excision subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Tendon sheath incision subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Tooth extraction subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Hip surgery subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
General disorders and administration site conditions				
Chills subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Abasia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Asthenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Catheter site haemorrhage subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Chest pain				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Chest discomfort				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cyst				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Infusion site extravasation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Device occlusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dysplasia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Face oedema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Facial pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Feeling abnormal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Feeling drunk				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Feeling hot				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gait disturbance				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
General physical health deterioration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hunger				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyperpyrexia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypothermia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Inflammation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Influenza like illness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Device failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Injection site swelling				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Local swelling				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Malaise				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Medical device complication				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mucosal inflammation				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Performance status decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Device leakage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Axillary pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Discomfort			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Suprapubic pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Immune system disorders			

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Milk allergy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Contrast media allergy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Hypogammaglobulinaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Social circumstances Physical assault subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Reproductive system and breast disorders Balanitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Breast pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Breast tenderness subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Genital rash subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Gynaecomastia			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Pelvic pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Perineal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Prostatic pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Prostatitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Pruritus genital subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Scrotal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Balanoposthitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Testicular pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Acute respiratory failure subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Asthma			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Alveolitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Atelectasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pleural effusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dysphonia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dyspnoea exertional				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dyspnoea paroxysmal nocturnal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Emphysema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Epistaxis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haemoptysis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hiccups				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Interstitial lung disease				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Laryngeal disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Laryngeal erythema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Laryngeal oedema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lung infiltration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nasal obstruction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Pleuritic pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pneumothorax				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Productive cough				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pulmonary embolism				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pulmonary fibrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pulmonary mass				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rales				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Respiration abnormal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Respiratory failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rhinorrhoea				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rhonchi				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sinus disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sleep apnoea syndrome				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sneezing				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Wheezing				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pneumonia aspiration				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bronchial obstruction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Apathy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bruxism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Delirium			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Depressed mood			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		

Disorientation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Emotional disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Agitation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Flat affect				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Initial insomnia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Insomnia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mood altered				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mood swings				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nightmare				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sleep disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Stress				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hallucination				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Daydreaming				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Restlessness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hepatobiliary disorders				
Hyperbilirubinaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cholelithiasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hepatic lesion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hepatic steatosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hepatomegaly				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hepatotoxicity				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypertransaminasaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Jaundice				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Non-alcoholic steatohepatitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pneumobilia				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Biliary colic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hepatic function abnormal			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Investigations			
Blood calcium decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood cholesterol increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bacterial test positive			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood albumin increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood calcium increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Heart rate increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood iron decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood potassium decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood potassium increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood pressure increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood pressure orthostatic decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood urine present				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cardiac murmur				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cardioactive drug level increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cystoscopy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Ejection fraction decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase abnormal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Heart rate irregular				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hepatic enzyme increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
International normalised ratio increased				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Liver function test abnormal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lymph node palpable				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lymphocyte count decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Norovirus test positive				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Respiratory rate increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Transaminases increased				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	7			
Troponin increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urine output decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vitamin B12 decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Weight decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Weight increased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
White blood cell count decreased				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Heart sounds abnormal			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haematocrit decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Accidental overdose			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ankle fracture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bone contusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Chest injury			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Limb injury			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Eye contusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Face injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	3			
Femur fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Foreign body in eye				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Fractured coccyx				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gastroenteritis radiation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hand fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Head injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Humerus fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Injection related reaction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Joint injury				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Laceration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Ligament sprain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Excoriation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lumbar vertebral fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Spinal compression fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Muscle injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Muscle strain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Overdose				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pelvic fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Periorbital contusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Post procedural haematuria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Post-traumatic pain				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Procedural hypotension				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Procedural nausea				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Procedural pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Procedural vomiting				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Radius fracture				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Rib fracture				
subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	2			
Skeletal injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin wound				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Multiple injuries				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Thoracic vertebral fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Toxicity to various agents				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Traumatic fracture				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urethral injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Wound				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Wound dehiscence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Wound secretion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Wrist fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Clavicle fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Incision site hypoaesthesia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Joint dislocation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lower limb fracture				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Meniscus injury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Road traffic accident				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Scapula fracture				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tendon rupture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Forearm fracture			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bundle branch block right			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cardiac failure			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cardiac failure congestive			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Chordae tendinae rupture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Coronary artery stenosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Diastolic dysfunction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Extrasystoles			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Left ventricular dysfunction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Bradycardia				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Atrial flutter				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Atrial fibrillation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mitral valve disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Aortic valve stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Angina pectoris				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Arrhythmia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Palpitations				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Myocardial ischaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Myocardial infarction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mitral valve prolapse				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Right ventricular dysfunction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Supraventricular extrasystoles			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sinus bradycardia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Angina unstable			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Atrioventricular block second degree			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Mitral valve incompetence			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ageusia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		

Amnesia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Ataxia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Burning sensation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypoglossal nerve paralysis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cauda equina syndrome				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cognitive disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dementia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dementia Alzheimer's type				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Disturbance in attention				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dizziness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dizziness postural				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dysaesthesia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Dysarthria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dysgeusia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dyskinesia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Head discomfort				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Headache				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hemiparesis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyperreflexia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypoaesthesia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Carpal tunnel syndrome				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypokinesia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Restless legs syndrome				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Loss of consciousness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Memory impairment				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Migraine				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nerve compression				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Neuralgia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Neuropathy peripheral				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Paraesthesia				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Parkinsonian gait				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Parkinson's disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Parosmia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Peripheral sensory neuropathy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Poor quality sleep				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Post herpetic neuralgia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Presyncope				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Radicular pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lethargy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Trigeminal neuralgia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sciatica				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Somnolence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Syncope				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tension headache				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tongue paralysis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Transient ischaemic attack				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tremor				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cerebellar atrophy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Cerebral atrophy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Facial paresis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Sensory disturbance subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
VIIth nerve paralysis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Visual field defect subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Blood and lymphatic system disorders Pancytopenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Lymphopenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Leukocytosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Anaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Bone marrow failure subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0			
Haemorrhagic anaemia				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pernicious anaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Motion sickness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hearing impaired			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Deafness neurosensory			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Deafness bilateral			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cerumen impaction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vertigo positional			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Ear pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye disorders			
Eye irritation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye inflammation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Exophthalmos			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Amaurosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lacrimation increased			

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Macular fibrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Night blindness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Ocular icterus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Optic ischaemic neuropathy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Photophobia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Retinal artery occlusion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Strabismus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Trichiasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vision blurred				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Visual acuity reduced				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Visual impairment				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vitreous floaters				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eyelid margin crusting			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Glaucoma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Iritis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vitreous haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Anal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Abdominal discomfort				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Apical granuloma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Barrett's oesophagus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Breath odour				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cheilitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Colitis microscopic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dental caries				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Abdominal pain upper				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Faecal incontinence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Eructation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Erosive oesophagitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Epigastric discomfort				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dysphagia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dry mouth				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Diverticulum intestinal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Faecaloma				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gastric ulcer				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gastric mucosa erythema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Frequent bowel movements				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Food poisoning				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Flatulence				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Faeces hard				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gingival bleeding				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Oesophageal pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gingival pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hiatus hernia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Inguinal hernia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Odynophagia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mouth ulceration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Melaena				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Localised intraabdominal fluid collection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lip oedema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lip dry				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Large intestine polyp				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gingival inflammation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Oesophagitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pancreatitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Paraesthesia oral				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Periodontal disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Proctalgia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rectal haemorrhage				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Retching				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Salivary hypersecretion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tongue disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Toothache				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Umbilical hernia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vomiting				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pancreatic disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sensitivity of teeth				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Anal fissure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Crohn's disease				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Diverticulum				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gastrointestinal disorder				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Glossodynia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lip swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oral discharge			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oral mucosal blistering			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Actinic keratosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Actinic prurigo			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blister			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cold sweat			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cutaneous lupus erythematosus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Decubitus ulcer				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dermal cyst				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dermatitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dermatitis acneiform				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dermatitis contact				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Diabetic foot				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dry skin				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Eczema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Granuloma annulare				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haemorrhage subcutaneous				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hair growth abnormal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Hypertrichosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Intertrigo				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Miliaria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Panniculitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pain of skin				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Petechiae				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Photodermatosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Psoriasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rash erythematous				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Rash macular				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rash papular				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rash pruritic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin exfoliation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin lesion				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nail disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Night sweats				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Onychoclasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Penile ulceration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin ulcer				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Swelling face				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Urticaria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sticky skin				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyperkeratosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nail growth abnormal				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Solar lentigo				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin atrophy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Renal and urinary disorders				
Incontinence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	8			
Bladder dysfunction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Bladder pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Bladder spasm				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Calculus bladder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Calculus ureteric				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dysuria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haematuria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Haemorrhage urinary tract				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hydronephrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lower urinary tract symptoms				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urinary hesitation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nephrolithiasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nocturia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pollakiuria				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Polyuria				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	2			
Prerenal failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Renal colic				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Renal failure				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Renal impairment				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Strangury				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Ureteric obstruction				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urethral dilatation				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urethral pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urethral stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urethritis noninfective				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urge incontinence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Micturition urgency				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urinary incontinence				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urinary retention				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urinary tract obstruction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urine odour abnormal			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cushingoid			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Goitre			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Thyroid mass			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hyperthyroidism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cushing's syndrome			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Coccydynia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Arthralgia			

subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	2			
Arthritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Arthropathy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Back pain				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Bone fistula				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Bone pain				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	2			
Bursitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Muscle atrophy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mobility decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Joint stiffness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Joint range of motion decreased				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Intervertebral disc protrusion				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Inguinal mass				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Groin pain				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Flank pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Muscle fatigue				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Myopathy				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Musculoskeletal stiffness				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Musculoskeletal pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Musculoskeletal discomfort				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Muscular weakness				
subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	2			
Muscle tightness				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Muscle spasms				
subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	3			
Myositis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tendonitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Osteoarthritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Osteonecrosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Osteonecrosis of jaw				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Osteopenia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Osteoporosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pain in extremity				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	3			
Synovitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Synovial cyst				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Spinal pain				

subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Spinal osteoarthritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Spinal column stenosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Scoliosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Plantar fasciitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pathological fracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pain in jaw				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Neck pain				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Trismus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tendon disorder				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dupuytren's contracture				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Foot deformity				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Limb discomfort				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rotator cuff syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Spinal deformity			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tendon calcification			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abscess neck			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Atypical mycobacterial infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	2		
Bronchopneumonia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal abscess			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Carbuncle			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Cellulitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Conjunctivitis infective				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Cystitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Diverticulitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Erysipelas				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Eye infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Eyelid infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Gastroenteritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Genital candidiasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gingival infection				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Gingivitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Helicobacter infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Mediastinitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Herpes zoster oticus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Infected cyst				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Infected dermal cyst				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Infection parasitic				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Influenza				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Injection site infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Labyrinthitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lip infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lobar pneumonia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Localised infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lung infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Herpes simplex				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nail infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Skin candida				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Onychomycosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Peritonitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Pulpitis dental				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rash pustular				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Scrotal abscess				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sialoadenitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	1			
Tooth abscess				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tinea cruris				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urethritis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	2			
Urosepsis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			

Skin infection			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Soft tissue infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tooth infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Arthritis infective			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Corona virus infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gastric infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oral fungal infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Staphylococcal skin infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Decreased appetite			

subjects affected / exposed	2 / 13 (15.38%)			
occurrences (all)	2			
Dehydration				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Diabetes mellitus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Dyslipidaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Fluid overload				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Fluid retention				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Gout				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypercalcaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypercholesterolaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyperglycaemia				
subjects affected / exposed	1 / 13 (7.69%)			
occurrences (all)	4			
Hyperkalaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyperlipidaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypernatraemia				

subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypoalbuminaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hypoglycaemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vitamin D deficiency				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vitamin B complex deficiency				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Type 2 diabetes mellitus				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Malnutrition				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Lactic acidosis				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Iron deficiency				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Increased appetite				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Hyponatraemia				
subjects affected / exposed	0 / 13 (0.00%)			
occurrences (all)	0			
Vitamin B12 deficiency				

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Folate deficiency			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported