



## Clinical trial results:

### A phase III Safety and Efficacy Study of ALZT-OP1 in Subjects with Evidence of Early Alzheimer's Disease.

#### Summary

EudraCT number	2015-002147-34
Trial protocol	HU CZ BG PL
Global end of trial date	13 November 2020

#### Results information

Result version number	v1 (current)
This version publication date	16 June 2022
First version publication date	16 June 2022

#### Trial information

##### Trial identification

Sponsor protocol code	AZT-001
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02547818
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	AZTherapies, Inc.
Sponsor organisation address	200 Clarendon Street, 17th Floor, Boston, United States, 02116
Public contact	Information Desk, AZTherapies, Inc., +1 (617) 318-3411, info@aztherapies.com
Scientific contact	Information Desk, AZTherapies, Inc., +1 (617) 318-3411, info@aztherapies.com

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 November 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 November 2020
Global end of trial reached?	Yes
Global end of trial date	13 November 2020
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of a combination treatment regimen (ALZT-OP1) of oral inhaled cromolyn, plus oral ibuprofen tablets, compared to each of the single component groups.

To evaluate the efficacy by Clinical Dementia Rating-Sum of Boxes (CDR-SB) assessment of a combination treatment regimen (ALZT-OP1) of oral inhaled cromolyn, plus oral ibuprofen tablets, compared to each of the single component groups.

To determine whether this combination treatment regimen slows down, arrests or reverses cognitive and functional decline in subjects with evidence of early Alzheimer's Disease (AD).

Protection of trial subjects:

Informed consent by the study participant and the requirement of a qualified study partner that also provided informed consent.

The Data and Safety Monitoring Board comprising of independent group of experts met at regular intervals to review the safety data while the trial was ongoing.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 72
Country: Number of subjects enrolled	Bulgaria: 17
Country: Number of subjects enrolled	Czechia: 108
Country: Number of subjects enrolled	Hungary: 22
Country: Number of subjects enrolled	Canada: 57
Country: Number of subjects enrolled	United States: 341
Country: Number of subjects enrolled	Australia: 2
Worldwide total number of subjects	619
EEA total number of subjects	219

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	135
From 65 to 84 years	484
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Subjects were screened against the inclusion/exclusion criteria of the study protocol. Key inclusion criteria included: 55-79 years old (inclusive); evidence of early AD as defined; CSF biomarker results consistent with early AD, including CSF A $\beta$ -42 levels  $\geq$ 180 pg/ml and  $\leq$ 690 pg/ml; CDR-Global = 0.5; Memory Box score must be at least 0.5.

### Period 1

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

Blinding implementation details:

This was a placebo-controlled, double blind, randomized study. To maintain blinding, study drug and placebo were prepared to look identical so that the subject, investigator, study staff, monitor, and sponsor remain blinded to treatment assignment. The study drug/placebo had unique coding to link subject assignments to actual treatment assignments at the end of the study. All investigators, subjects, site personnel, sponsor and CRO study team, were blinded to the medication codes.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Group 1

Arm description:

ALZT-OP1a (q.d. inhalation of active cromolyn via DPI + q.d. oral placebo tablet)

Arm type	single active component - cromolyn
Investigational medicinal product name	cromolyn
Investigational medicinal product code	ALZT-OP1a
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

ALZT-OP1a (cromolyn) was supplied as a 17.1 mg powder blend encapsulated for administration via oral inhalation using a mono-dose dry powder inhaler (DPI) for once daily administration. Subjects were asked to complete 72 weeks of daily dosing.

Investigational medicinal product name	oral placebo
Investigational medicinal product code	ALZT-OP1b placebo
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ALZT-OP1b Placebo was supplied as an enterically coated tablet for once daily oral administration. Subjects were asked to complete 72 weeks of daily dosing.

<b>Arm title</b>	Group 2
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Arm description:

ALZT-OP1 double active therapy (q.d. inhalation of active cromolyn via DPI + q.d. ibuprofen oral active tablet)

Arm type	Experimental
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Investigational medicinal product name	cromolyn
Investigational medicinal product code	ALZT-OP1a
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

ALZT-OP1a (cromolyn) was supplied as a 17.1 mg powder blend encapsulated for administration via oral inhalation using a mono-dose dry powder inhaler (DPI) for once daily administration. Subjects were asked to complete 72 weeks of daily dosing.

Investigational medicinal product name	ibuprofen
Investigational medicinal product code	ALZT-OP1b
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ALZT-OP1b (ibuprofen) was supplied as an enterically coated 10 mg tablet for once daily oral administration. Subjects were asked to complete 72 weeks of daily dosing

<b>Arm title</b>	Group 3
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Arm description:

ALZT-OP1b (q.d. inhalation of placebo via DPI + q.d. oral active ibuprofen tablet)

Arm type	single active component - ibuprofen
Investigational medicinal product name	ibuprofen
Investigational medicinal product code	ALZT-OP1b
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ALZT-OP1b (ibuprofen) was supplied as an enterically coated 10 mg tablet for once daily oral administration. Subjects were asked to complete 72 weeks of daily dosing

Investigational medicinal product name	inhalation placebo
Investigational medicinal product code	ALZT-OP1a placebo
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

ALZT-OP1a Placebo was supplied as a powder blend encapsulated for once daily administration via oral inhalation using a mono-dose dry powder inhaler. Subjects were asked to complete 72 weeks of daily dosing.

<b>Arm title</b>	Group 4
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Arm description:

q.d. inhalation of placebo via DPI + q.d. oral placebo tablet

Arm type	Placebo
Investigational medicinal product name	inhalation placebo
Investigational medicinal product code	ALZT-OP1a placebo
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

ALZT-OP1a Placebo was supplied as a powder blend encapsulated for once daily administration via oral inhalation using a mono-dose dry powder inhaler. Subjects were asked to complete 72 weeks of daily dosing.

Investigational medicinal product name	oral placebo
Investigational medicinal product code	ALZT-OP1b placebo
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ALZT-OP1b Placebo was supplied as an enterically coated tablet for once daily oral administration. Subjects were asked to complete 72 weeks of daily dosing.

<b>Number of subjects in period 1</b>	Group 1	Group 2	Group 3
Started	153	153	160
Completed	117	116	128
Not completed	36	37	32
Adverse event, serious fatal	3	1	2
Physician decision	-	-	-
Study terminated by Sponsor	1	-	1
Incorrect IP dispense	-	-	-
Abnormal lab results at baseline	-	-	-
Consent withdrawn by subject	16	20	15
Adverse event, non-fatal	7	5	6
Progressive Disease	-	-	1
Non-compliance with study drug	5	-	1
Site closed	-	1	-
Lost to follow-up	3	2	2
Lack of efficacy	1	1	1
Protocol deviation	-	7	3

<b>Number of subjects in period 1</b>	Group 4
Started	153
Completed	118
Not completed	35
Adverse event, serious fatal	-
Physician decision	1
Study terminated by Sponsor	-
Incorrect IP dispense	1
Abnormal lab results at baseline	1
Consent withdrawn by subject	19
Adverse event, non-fatal	5
Progressive Disease	1
Non-compliance with study drug	3

Site closed	1
Lost to follow-up	-
Lack of efficacy	3
Protocol deviation	-

## Baseline characteristics

### Reporting groups

Reporting group title	Group 1
Reporting group description: ALZT-OP1a (q.d. inhalation of active cromolyn via DPI + q.d. oral placebo tablet)	
Reporting group title	Group 2
Reporting group description: ALZT-OP1 double active therapy (q.d. inhalation of active cromolyn via DPI + q.d. ibuprofen oral active tablet)	
Reporting group title	Group 3
Reporting group description: ALZT-OP1b (q.d. inhalation of placebo via DPI + q.d. oral active ibuprofen tablet)	
Reporting group title	Group 4
Reporting group description: q.d. inhalation of placebo via DPI + q.d. oral placebo tablet	

Reporting group values	Group 1	Group 2	Group 3
Number of subjects	153	153	160
Age categorical			
AZT-001 study participants were aged 55-79 years, inclusive.			
Units: Subjects			
Adults (18-64 years)	33	35	35
From 65-84 years	120	118	125
Gender categorical			
Units: Subjects			
Female	75	95	92
Male	78	58	68

Reporting group values	Group 4	Total	
Number of subjects	153	619	
Age categorical			
AZT-001 study participants were aged 55-79 years, inclusive.			
Units: Subjects			
Adults (18-64 years)	32	135	
From 65-84 years	121	484	
Gender categorical			
Units: Subjects			
Female	72	334	
Male	81	285	

### Subject analysis sets

Subject analysis set title	mITT
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: The mITT as a primary analysis set is defined as all randomized subjects who have a baseline CDR-SB as well as a CDR-SB post-baseline observation.	



<b>Reporting group values</b>	mITT		
Number of subjects	594		
Age categorical			
AZT-001 study participants were aged 55-79 years, inclusive.			
Units: Subjects			
Adults (18-64 years)	125		
From 65-84 years	469		
Gender categorical			
Units: Subjects			
Female	320		
Male	274		

## End points

### End points reporting groups

Reporting group title	Group 1
Reporting group description: ALZT-OP1a (q.d. inhalation of active cromolyn via DPI + q.d. oral placebo tablet)	
Reporting group title	Group 2
Reporting group description: ALZT-OP1 double active therapy (q.d. inhalation of active cromolyn via DPI + q.d. ibuprofen oral active tablet)	
Reporting group title	Group 3
Reporting group description: ALZT-OP1b (q.d. inhalation of placebo via DPI + q.d. oral active ibuprofen tablet)	
Reporting group title	Group 4
Reporting group description: q.d. inhalation of placebo via DPI + q.d. oral placebo tablet	
Subject analysis set title	mITT
Subject analysis set type	Modified intention-to-treat
Subject analysis set description: The mITT as a primary analysis set is defined as all randomized subjects who have a baseline CDR-SB as well as a CDR-SB post-baseline observation.	

### Primary: Mean change from baseline to Week 72 in points scored on the CDR-SB (Primary contrast 1)

End point title	Mean change from baseline to Week 72 in points scored on the CDR-SB (Primary contrast 1) <sup>[1]</sup>
End point description: Mean change from baseline to Week 72 in points scored on the CDR-SB for the following main contrast:  - Group 2 (cromolyn active+Ibuprofen active) vs. Group 1 (cromolyn sodium active+Ibuprofen placebo)	
End point type	Primary
End point timeframe: Baseline to Week 72	
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: AZT-001 was designed as a factorial study in which the two primary contrasts consisted of comparing the combination treatment (Group 2; cromolyn + ibuprofen) compared to each of the single active component arms: Group 2 (combination) vs Group 1 (cromolyn active) and Group 2 (combination) vs Group 3 (ibuprofen active). A placebo arm (group 4) was included in the study. Secondary contrasts provided comparison of Group 2 (combination) vs Group 4 (placebo) and Group 1 (cromolyn active) vs Group 4.

End point values	Group 1	Group 2	mITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	147	145	292	
Units: CDR-SB				
least squares mean (confidence interval 95%)	2.17 (1.64 to 2.69)	2.33 (1.80 to 2.85)	0.16 (-0.58 to 0.90)	

## Statistical analyses

Statistical analysis title	MMRM Analysis
Statistical analysis description: Results are based on a MMRM model including the fixed effects treatment, visit, treatment by visit interaction, region and the covariates APOe4, anti-dementia drug use, baseline CDR-SB and age assuming an unstructured correlation matrix.	
Comparison groups	Group 1 v Group 2
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.675
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	18
Variability estimate	Standard error of the mean

### Primary: Mean change from baseline to Week 72 in points scored on the CDR-SB (Primary contrast 2)

End point title	Mean change from baseline to Week 72 in points scored on the CDR-SB (Primary contrast 2) <sup>[2]</sup>
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End point description:

Mean change from baseline to Week 72 in points scored on the CDR-SB for the following main contrast:

- Group 2 (cromolyn active+Ibuprofen active) vs. Group 3 (cromolyn placebo+Ibuprofen active)

End point type	Primary
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End point timeframe:

Baseline to Week 72

Notes:

[2] - 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: AZT-001 was designed as a factorial study in which the two primary contrasts consisted of comparing the combination treatment (Group 2; cromolyn + ibuprofen) compared to each of the single active component arms: Group 2 (combination) vs Group 1 (cromolyn active) and Group 2 (combination) vs Group 3 (ibuprofen active). A placebo arm (group 4) was included in the study. Secondary contrasts provided comparison of Group 2 (combination) vs Group 4 (placebo) and Group 1 (cromolyn active) vs Group 4.

End point values	Group 2	Group 3	mITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	145	155	300	
Units: CDR-SB				
least squares mean (confidence interval 95%)	2.33 (1.80 to 2.85)	1.92 (1.42 to 2.43)	0.40 (-0.32 to 1.13)	

## Statistical analyses

<b>Statistical analysis title</b>	MMRM Analysis
Statistical analysis description: Results are based on a MMRM model including the fixed effects treatment, visit, treatment by visit interaction, region and the covariates APOe4, anti-dementia drug use, baseline CDR-SB and age assuming an unstructured correlation matrix.	
Comparison groups	Group 2 v Group 3
Number of subjects included in analysis	300
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2764
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	18
Variability estimate	Standard error of the mean

### Secondary: Mean change from baseline to Week 72 in points scored on the CDR-SB (Secondary contrast 1)

End point title	Mean change from baseline to Week 72 in points scored on the CDR-SB (Secondary contrast 1) <sup>[3]</sup>
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End point description:

Mean change from baseline to Week 72 in points scored on the CDR-SB for the following secondary contrast:

- Group 2 (cromolyn active+Ibuprofen active) vs. Group 4 (cromolyn placebo+Ibuprofen placebo);

End point type	Secondary
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End point timeframe:

Baseline to Week 72

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: AZT-001 was designed as a factorial study in which the two primary contrasts consisted of comparing the combination treatment (Group 2; cromolyn + ibuprofen) compared to each of the single active component arms: Group 2 (combination) vs Group 1 (cromolyn active) and Group 2 (combination) vs Group 3 (ibuprofen active). A placebo arm (group 4) was included in the study. Secondary contrasts provided comparison of Group 2 (combination) vs Group 4 (placebo) and Group 1 (cromolyn active) vs Group 4.

End point values	Group 2	Group 4	mITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	145	147	292	
Units: CDR-SB				
least squares mean (confidence interval 95%)	2.33 (1.80 to 2.85)	2.22 (1.70 to 2.74)	0.11 (-0.63 to 0.84)	

## Statistical analyses

<b>Statistical analysis title</b>	MMRM Analysis
Statistical analysis description:	
Results are based on a MMRM model including the fixed effects treatment, visit, treatment by visit interaction, region and the covariates APOe4, anti-dementia drug use, baseline CDR-SB and age assuming an unstructured correlation matrix.	
Comparison groups	Group 2 v Group 4
Number of subjects included in analysis	292
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.776
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	18
Variability estimate	Standard error of the mean

## Secondary: Mean change from baseline to Week 72 in points scored on the CDR-SB (Secondary contrast 2)

End point title	Mean change from baseline to Week 72 in points scored on the CDR-SB (Secondary contrast 2) <sup>[4]</sup>
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End point description:

Mean change from baseline to Week 72 in points scored on the CDR-SB for the following secondary contrast:

- Group 1 (cromolyn active+Ibuprofen placebo) vs. Group 4 (cromolyn sodium placebo+Ibuprofen placebo)

End point type	Secondary
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End point timeframe:

Baseline to Week 72

Notes:

[4] - 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: AZT-001 was designed as a factorial study in which the two primary contrasts consisted of comparing the combination treatment (Group 2; cromolyn + ibuprofen) compared to each of the single active component arms: Group 2 (combination) vs Group 1 (cromolyn active) and Group 2 (combination) vs Group 3 (ibuprofen active). A placebo arm (group 4) was included in the study. Secondary contrasts provided comparison of Group 2 (combination) vs Group 4 (placebo) and Group 1 (cromolyn active) vs Group 4.

End point values	Group 1	Group 4	mITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	147	147	294	
Units: CDR-SB				
least squares mean (confidence interval 95%)	2.17 (1.64 to 2.69)	2.22 (1.70 to 2.74)	-0.05 (-0.79 to 0.69)	

## Statistical analyses

Statistical analysis title	MMRM Analysis
Statistical analysis description:	
Results are based on a MMRM model including the fixed effects treatment, visit, treatment by visit interaction, region and the covariates APOe4, anti-dementia drug use, baseline CDR-SB and age assuming an unstructured correlation matrix.	
Comparison groups	Group 1 v Group 4
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8912
Method	Mixed models analysis
Parameter estimate	Mean difference (net)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	18
Variability estimate	Standard error of the mean

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

3 September 2015 to 13 November 2020

Adverse event reporting additional description:

Date of consent to last patient last visit.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1E
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### Reporting groups

Reporting group title	Group 1
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Reporting group description:

ALZT-OP1a (q.d. inhalation of active cromolyn via DPI + q.d. oral placebo tablet)

Reporting group title	Group 2
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Reporting group description:

ALZT-OP1 double active therapy (q.d. inhalation of active cromolyn via DPI + q.d. ibuprofen oral active tablet)

Reporting group title	Group 3
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Reporting group description:

ALZT-OP1b (q.d. inhalation of placebo via DPI + q.d. oral active ibuprofen tablet)

Reporting group title	Group 4
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Reporting group description:

q.d. inhalation of placebo via DPI + q.d. oral placebo tablet

Serious adverse events	Group 1	Group 2	Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 154 (11.69%)	15 / 153 (9.80%)	16 / 160 (10.00%)
number of deaths (all causes)	6	2	3
number of deaths resulting from adverse events	6	2	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Endometrial cancer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Metastases to bone			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Metastatic uterine cancer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Prostate cancer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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			
Arterial stenosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (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
Asthenia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
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	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1



Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Pulmonary embolism			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Pulmonary infarction			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary thrombosis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
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			
Aggression			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (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
Depression			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Agitation			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Anxiety			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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

Delusion			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	3 / 160 (1.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Cervical vertebral fracture			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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

Concussion			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Head injury			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Traumatic intracranial haemorrhage			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Dolichocolon			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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

Acute myocardial infarction			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Cardiac failure congestive			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Myocardial infarction			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sinus arrest			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Nervous system disorders			
Dementia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebrovascular accident			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Dementia Alzheimer's type			

subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Ischaemic stroke			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thrombotic stroke			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Rectal haemorrhage			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Abdominal pain			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (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
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (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
Pancreatic mass			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
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			
Cholecystitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Urinary tract obstruction			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Diabetic metabolic decompensation			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
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			
Osteoarthritis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
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	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
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 instability			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (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

Appendicitis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (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
Diverticulitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (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
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Pneumonia chlamydial			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (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
Pneumonia influenzal			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

<b>Serious adverse events</b>	Group 4		
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 152 (9.87%)		
number of deaths (all causes)	3		
number of deaths resulting from adverse events	3		



Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Endometrial cancer			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastatic uterine cancer			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Prostate cancer			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Arterial stenosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Death			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary infarction			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary thrombosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Depression			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Agitation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Delusion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pubis fracture			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar vertebral fracture			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Post lumbar puncture syndrome subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acetabulum fracture subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervical vertebral fracture subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Concussion subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Head injury subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic intracranial haemorrhage subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			

Dolichocolon			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Atrial fibrillation			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus arrest			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Dementia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Dementia Alzheimer's type			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalopathy			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombotic stroke			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			

Deafness			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Rectal haemorrhage			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 152 (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 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic mass			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Cholelithiasis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 152 (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 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal instability			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia chlamydial			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia influenzal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	0 / 152 (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: 0.6 %

<b>Non-serious adverse events</b>	Group 1	Group 2	Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	76 / 154 (49.35%)	83 / 153 (54.25%)	79 / 160 (49.38%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Basal cell carcinoma			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	0	2	1
Colon adenoma			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Endometrial cancer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Haemangioma of skin			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Kidney angiomyolipoma			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Rectal adenoma			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Seborrhoeic keratosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	3 / 160 (1.88%)
occurrences (all)	0	0	3
Skin papilloma			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Aortic arteriosclerosis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Circulatory collapse			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Deep vein thrombosis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	3 / 154 (1.95%)	3 / 153 (1.96%)	2 / 160 (1.25%)
occurrences (all)	3	4	2

Hypotension			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Iliac vein occlusion			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Varicose ulceration			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Varicose vein			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Vena cava thrombosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Cardiac pacemaker insertion			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Cataract operation			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	2	1
Cyst removal			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Hip surgery			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Intraocular lens implant			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Myringotomy			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Nephrectomy			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Shoulder arthroplasty			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Skin lesion excision			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Skin neoplasm excision			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Tooth extraction			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Uterine dilation and curettage			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Condition aggravated			
subjects affected / exposed	6 / 154 (3.90%)	10 / 153 (6.54%)	9 / 160 (5.63%)
occurrences (all)	8	12	11
Asthenia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Fatigue			

subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Feeling abnormal			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	0	2	1
Influenza like illness			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	2
Pain			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Puncture site pain			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	0	2	1
Pyrexia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Ulcer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	2 / 160 (1.25%) 4
Hypersensitivity subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Multiple allergies subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Reproductive system and breast disorders			
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	2 / 154 (1.30%) 2	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Testicular pain subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Uterine cyst subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	7 / 154 (4.55%) 7	7 / 153 (4.58%) 7	5 / 160 (3.13%) 5
Asthma subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Bronchitis chronic subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Epistaxis subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Dry throat subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Dyspnoea			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Increased upper airway secretion			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Productive cough			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Pulmonary mass			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Rales			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Rhinitis allergic			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	3	0	1
Sinus congestion			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	3	0
Suffocation feeling			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Throat irritation			



subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Wheezing			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 154 (1.30%)	5 / 153 (3.27%)	8 / 160 (5.00%)
occurrences (all)	2	5	10
Abnormal dreams			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Adjustment disorder with depressed mood			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Aggression			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Agitation			
subjects affected / exposed	1 / 154 (0.65%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	2	2	1
Confusional state			
subjects affected / exposed	2 / 154 (1.30%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	2	2	1
Delirium			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Delusion			
subjects affected / exposed	0 / 154 (0.00%)	3 / 153 (1.96%)	2 / 160 (1.25%)
occurrences (all)	0	4	2
Delusion of replacement			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Delusional disorder, unspecified type			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Depression			
subjects affected / exposed	2 / 154 (1.30%)	2 / 153 (1.31%)	4 / 160 (2.50%)
occurrences (all)	2	2	4
Depressive symptom			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Dermatillomania			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Disorientation			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Hallucination, visual			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Illusion			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 154 (1.30%)	3 / 153 (1.96%)	4 / 160 (2.50%)
occurrences (all)	2	3	4
Irritability			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Mood swings			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Paranoia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Rapid eye movement sleep behaviour disorder			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Restlessness			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	2
Aortic bruit			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	2
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Blood bilirubin increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Blood cholesterol increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Blood creatinine increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Blood glucose decreased			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Blood glucose increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Blood testosterone decreased			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Blood urine present			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Breath sounds abnormal			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0

Cardiac murmur			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Coronavirus test positive			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram P wave abnormal			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Glucose urine present			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Haematocrit decreased			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Haemoglobin decreased			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Heart rate irregular			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Liver function test abnormal			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0

Liver function test increased subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Mean cell haemoglobin concentration decreased subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Mean cell haemoglobin decreased subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Mean cell haemoglobin increased subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Mean cell volume decreased subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Mean cell volume increased subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Prostatic specific antigen increased subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Protein urine present subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Pupillary light reflex tests abnormal subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
QRS axis abnormal subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 2
Red blood cell sedimentation rate increased subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Red blood cells urine positive			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Red cell distribution width increased			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Reticulocyte count decreased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Reticulocyte count increased			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Smear cervix abnormal			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Urine analysis abnormal			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	0	0	2
White blood cell count increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	5 / 154 (3.25%)	4 / 153 (2.61%)	7 / 160 (4.38%)
occurrences (all)	5	4	7
Contusion			

subjects affected / exposed	5 / 154 (3.25%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	5	2	0
Accidental overdose			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Alcohol poisoning			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Animal bite			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	1	1	2
Arthropod sting			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Burns first degree			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Burns second degree			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Exposure to toxic agent			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Ear injury			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Eyelid injury			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Hand fracture			



subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Head injury			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Humerus fracture			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	2
Incorrect route of drug administration			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Infusion related reaction	Additional description: Infusion Reaction to carboplatin infusion for cancer treatment.		
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Injury			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Laceration			
subjects affected / exposed	2 / 154 (1.30%)	2 / 153 (1.31%)	2 / 160 (1.25%)
occurrences (all)	3	2	2
Ligament sprain			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Mouth injury			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Post lumbar puncture syndrome			
subjects affected / exposed	3 / 154 (1.95%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	3	1	2

Procedural pain subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	1 / 160 (0.63%) 1
Pubis fracture subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Radius fracture subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Road traffic accident subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Scratch subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Skin abrasion subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	1 / 160 (0.63%) 1
Subdural haematoma subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Traumatic haemorrhage subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Upper limb fracture subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Wrist fracture subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Cardiac disorders			

Acute myocardial infarction subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	2 / 153 (1.31%) 2	1 / 160 (0.63%) 1
Atrioventricular block first degree subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Atrioventricular block second degree subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Bradycardia subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Cardiogenic shock subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	2 / 153 (1.31%) 2	0 / 160 (0.00%) 0
Sinus node dysfunction subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Supraventricular tachycardia subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Tachyarrhythmia subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Ventricular extrasystoles subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	1 / 160 (0.63%) 1
Nervous system disorders Dementia Alzheimer's type			

subjects affected / exposed	9 / 154 (5.84%)	9 / 153 (5.88%)	8 / 160 (5.00%)
occurrences (all)	9	10	8
Headache			
subjects affected / exposed	7 / 154 (4.55%)	5 / 153 (3.27%)	10 / 160 (6.25%)
occurrences (all)	7	5	11
Dizziness			
subjects affected / exposed	0 / 154 (0.00%)	5 / 153 (3.27%)	7 / 160 (4.38%)
occurrences (all)	0	6	8
Cognitive disorder			
subjects affected / exposed	5 / 154 (3.25%)	3 / 153 (1.96%)	1 / 160 (0.63%)
occurrences (all)	6	3	1
Amputation stump pain			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	1	0	2
Balance disorder			
subjects affected / exposed	2 / 154 (1.30%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	2	2	1
Carpal tunnel syndrome			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Dementia			
subjects affected / exposed	0 / 154 (0.00%)	3 / 153 (1.96%)	0 / 160 (0.00%)
occurrences (all)	0	4	0
Dementia with Lewy bodies			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Diabetic neuropathy			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Gait apraxia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	2
Hypersomnia			

subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Hyposmia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Ischaemic stroke			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Nerve compression			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Nystagmus			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Occipital neuralgia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	0	2	1
Parkinsonian rest tremor			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Parkinsonism			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Presyncope			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Somnolence			

subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 154 (0.00%)	3 / 153 (1.96%)	2 / 160 (1.25%)
occurrences (all)	0	3	3
Tardive dyskinesia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Transient global amnesia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 154 (1.95%)	3 / 153 (1.96%)	3 / 160 (1.88%)
occurrences (all)	3	3	3
Leukocytosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	0	0	2
Microcytic anaemia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
White blood cell disorder			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Deafness bilateral			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Deafness unilateral			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Sudden hearing loss			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	3 / 154 (1.95%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	3	1	2
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Glaucoma			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Lacrimation increased			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1

Miosis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Retinal detachment			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	3 / 160 (1.88%)
occurrences (all)	0	1	3
Abdominal discomfort			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	3
Abdominal pain			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	2
Anal incontinence			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Cheilitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Coeliac disease			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Constipation			



subjects affected / exposed	2 / 154 (1.30%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	2	1	1
Eructation			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Diverticulum			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Diverticulum intestinal			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Faecal incontinence			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Faeces hard			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Gastric ulcer			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Haemorrhoids			

subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	2	0	1
Hiatus hernia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	2	0	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Large intestine polyp			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	2	0	1
Nausea			
subjects affected / exposed	4 / 154 (2.60%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	4	1	2
Oesophagitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Peptic ulcer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Salivary gland disorder			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Tooth impacted			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Vomiting			

subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	2 / 153 (1.31%) 2	1 / 160 (0.63%) 1
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	2
Cholelithiasis			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Hepatic cyst			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Cutis laxa			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Diabetic foot			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Erythema			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Hyperkeratosis			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Hypertrichosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Papule			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Petechiae			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Photodermatitis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	2 / 160 (1.25%)
occurrences (all)	0	2	2
Rash			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	2	0	2
Rash pruritic			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Telangiectasia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Urticaria chronic			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Xanthelasma			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 154 (0.65%)	2 / 153 (1.31%)	2 / 160 (1.25%)
occurrences (all)	1	2	2
Hydronephrosis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	0	2	1
Incontinence			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1

Leukocyturia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Renal cyst			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Ureterolithiasis			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Urinary incontinence			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Urinary retention			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Urinary tract inflammation			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Endocrine disorders			
Endocrine disorders			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	3 / 160 (1.88%)
occurrences (all)	2	0	3
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	5 / 154 (3.25%)	1 / 153 (0.65%)	3 / 160 (1.88%)
occurrences (all)	5	1	3
Arthralgia			

subjects affected / exposed	4 / 154 (2.60%)	1 / 153 (0.65%)	3 / 160 (1.88%)
occurrences (all)	5	1	5
Arthritis			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	1 / 160 (0.63%)
occurrences (all)	0	2	1
Fracture pain			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Facial asymmetry			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	0	0	2
Musculoskeletal pain			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	2	0	1
Myalgia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	1	0	2
Osteoarthritis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	2 / 160 (1.25%)
occurrences (all)	0	1	2
Osteopenia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Osteoporosis			

subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Plantar fasciitis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Soft tissue mass			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Spinal deformity			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Spinal instability			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Spinal osteoarthritis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	0	0	2
Spinal pain			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	0	0	2
Tendonitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Tenosynovitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	2
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	7 / 154 (4.55%)	7 / 153 (4.58%)	12 / 160 (7.50%)
occurrences (all)	8	8	13



Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 154 (4.55%) 7	10 / 153 (6.54%) 12	6 / 160 (3.75%) 6
Nasopharyngitis subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	3 / 153 (1.96%) 3	6 / 160 (3.75%) 8
Acute sinusitis subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Borrelia infection subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	4 / 154 (2.60%) 4	4 / 153 (2.61%) 4	0 / 160 (0.00%) 0
Bronchitis viral subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	1 / 153 (0.65%) 1	2 / 160 (1.25%) 2
Clostridium difficile colitis subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 154 (0.00%) 0	1 / 153 (0.65%) 1	0 / 160 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	1 / 154 (0.65%) 1	0 / 153 (0.00%) 0	0 / 160 (0.00%) 0
Fungal skin infection subjects affected / exposed occurrences (all)	2 / 154 (1.30%) 2	0 / 153 (0.00%) 0	2 / 160 (1.25%) 2

Diverticulitis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Gastroenteritis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Gingival abscess			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Herpes virus infection			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Influenza			
subjects affected / exposed	2 / 154 (1.30%)	2 / 153 (1.31%)	2 / 160 (1.25%)
occurrences (all)	2	2	2
Localised infection			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Onychomycosis			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1

Oral herpes			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Otitis media chronic			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Periodontitis			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 154 (0.00%)	3 / 153 (1.96%)	1 / 160 (0.63%)
occurrences (all)	0	3	1
Respiratory tract infection			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	1	0	2
Tooth abscess			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0

Vaginal infection			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	2 / 160 (1.25%)
occurrences (all)	0	0	3
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Dehydration			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	1	1	0
Diabetes mellitus			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	1 / 154 (0.65%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	1	0	0
Hypercholesterolaemia			
subjects affected / exposed	1 / 154 (0.65%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	1	1	1
Hyperglycaemia			
subjects affected / exposed	2 / 154 (1.30%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	0 / 160 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 154 (0.00%)	1 / 153 (0.65%)	1 / 160 (0.63%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	0 / 154 (0.00%)	2 / 153 (1.31%)	0 / 160 (0.00%)
occurrences (all)	0	2	0
Hypomagnesaemia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	0 / 160 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	0 / 154 (0.00%)	0 / 153 (0.00%)	1 / 160 (0.63%)
occurrences (all)	0	0	1

<b>Non-serious adverse events</b>	Group 4		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	77 / 152 (50.66%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Basal cell carcinoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Colon adenoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Endometrial cancer			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Haemangioma of skin			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Kidney angiomyolipoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rectal adenoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Seborrhoeic keratosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Skin papilloma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Squamous cell carcinoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Aortic arteriosclerosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Circulatory collapse			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Haematoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Iliac vein occlusion			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Thrombophlebitis			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Varicose ulceration			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Varicose vein			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Vena cava thrombosis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Surgical and medical procedures			
Cardiac pacemaker insertion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cataract operation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cyst removal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hip surgery			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Intraocular lens implant			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	2		
Myringotomy			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Nephrectomy			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Shoulder arthroplasty			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Skin lesion excision			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Skin neoplasm excision			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Tooth extraction			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Uterine dilation and curettage			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Condition aggravated			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	6		
Asthenia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Chest discomfort			



subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Feeling abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gait disturbance			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	5		
Pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Puncture site pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pyrexia			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Ulcer			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypersensitivity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Multiple allergies			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Testicular pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Uterine cyst			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 152 (4.61%)		
occurrences (all)	7		
Asthma			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Bronchitis chronic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Epistaxis			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	2		
Dry throat			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Increased upper airway secretion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pulmonary mass			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rales			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Sinus congestion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Suffocation feeling			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	7		
Abnormal dreams			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Aggression			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Agitation			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Confusional state			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Delirium			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	2		
Delusion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Delusion of replacement			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Delusional disorder, unspecified type			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Depressed mood			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Depressive symptom			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dermatillomania			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hallucination, visual			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Illusion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Insomnia			

subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Irritability			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Mood swings			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Nervousness			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Nightmare			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Paranoia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Persistent depressive disorder			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rapid eye movement sleep behaviour disorder			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Sleep disorder			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Aortic bruit			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood bilirubin increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood cholesterol increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood glucose decreased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood glucose increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood potassium increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood pressure increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood testosterone decreased			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Blood urine present			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Breath sounds abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cardiac murmur			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Coronavirus test positive			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
C-reactive protein increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Electrocardiogram QT prolonged			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	4		
Electrocardiogram T wave inversion			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Electrocardiogram P wave abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Glucose urine present			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haematocrit decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Heart rate irregular			



subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hepatic enzyme increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Liver function test abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Liver function test increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Mean cell haemoglobin concentration decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Mean cell haemoglobin decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Mean cell haemoglobin increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Mean cell volume decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Mean cell volume increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Prostatic specific antigen increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Protein urine present			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Pupillary light reflex tests abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

QRS axis abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Red blood cells urine positive			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Red cell distribution width increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Reticulocyte count decreased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Reticulocyte count increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Smear cervix abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Urine analysis abnormal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Urine leukocyte esterase positive			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
White blood cells urine positive			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	5		
Contusion			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Accidental overdose			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Alcohol poisoning			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Animal bite			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Arthropod sting			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Burns first degree			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Burns second degree			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Exposure to toxic agent			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Foot fracture			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Ear injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Eyelid injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hand fracture			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Head injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Humerus fracture			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Incorrect route of drug administration			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Infusion related reaction	Additional description: Infusion Reaction to carboplatin infusion for cancer treatment.		
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Mouth injury			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Post lumbar puncture syndrome			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Procedural pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pubis fracture			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Radius fracture			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Road traffic accident			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Scratch			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Subdural haematoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Traumatic haemorrhage			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Upper limb fracture			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		

Wrist fracture subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Congenital, familial and genetic disorders Hydrocele subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Cardiac disorders Acute myocardial infarction subjects affected / exposed occurrences (all)  Atrial fibrillation subjects affected / exposed occurrences (all)  Atrioventricular block first degree subjects affected / exposed occurrences (all)  Atrioventricular block second degree subjects affected / exposed occurrences (all)  Bradycardia subjects affected / exposed occurrences (all)  Cardiogenic shock subjects affected / exposed occurrences (all)  Sinus bradycardia subjects affected / exposed occurrences (all)  Sinus node dysfunction subjects affected / exposed occurrences (all)  Supraventricular tachycardia subjects affected / exposed occurrences (all)  Tachyarrhythmia	0 / 152 (0.00%) 0  0 / 152 (0.00%) 0  0 / 152 (0.00%) 0  2 / 152 (1.32%) 2  1 / 152 (0.66%) 1  0 / 152 (0.00%) 0  0 / 152 (0.00%) 0  0 / 152 (0.00%) 0  1 / 152 (0.66%) 1		

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dementia Alzheimer's type			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Headache			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences (all)	4		
Dizziness			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Cognitive disorder			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Amputation stump pain			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Aphasia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Balance disorder			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Carpal tunnel syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dementia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dementia with Lewy bodies			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Diabetic neuropathy			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gait apraxia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypersomnia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hyposmia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Ischaemic stroke			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Memory impairment			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Nerve compression			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Nystagmus			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Occipital neuralgia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Parkinsonian rest tremor			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Parkinsonism			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		



Presyncope			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Syncope			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tardive dyskinesia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Transient global amnesia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Leukocytosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Microcytic anaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Normochromic normocytic anaemia			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
White blood cell disorder			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Deafness bilateral			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Deafness unilateral			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Sudden hearing loss			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Cataract			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Eye irritation			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Glaucoma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Miosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Retinal detachment			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Visual acuity reduced			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Abdominal discomfort			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Abdominal pain lower			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Anal incontinence			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Cheilitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Coeliac disease			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Eructation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Diverticulum			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Diverticulum intestinal			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Faecal incontinence			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Faeces hard			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gastric ulcer			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Gastrointestinal sounds abnormal			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hiatus hernia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Inguinal hernia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Irritable bowel syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Large intestine polyp			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Oesophagitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Peptic ulcer			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Salivary gland disorder			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Tooth impacted subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Vomiting subjects affected / exposed occurrences (all)	3 / 152 (1.97%) 3		
Hepatobiliary disorders Cholecystitis subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Cholelithiasis subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Hepatic cyst subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Cutis laxa subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Decubitus ulcer subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Dermatitis subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Dermatitis contact subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Diabetic foot			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Haemorrhage subcutaneous			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hyperkeratosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypertrichosis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Miliaria			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Papule			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Photodermatitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Rash pruritic			

subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Scab			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Telangiectasia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	2		
Urticaria chronic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Xanthelasma			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Chronic kidney disease			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Haematuria			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Hydronephrosis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		



Hypertonic bladder subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Incontinence subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Leukocyturia subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Nephrolithiasis subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Pollakiuria subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Renal cyst subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Ureterolithiasis subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Urinary incontinence subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Urinary retention subjects affected / exposed occurrences (all)	1 / 152 (0.66%) 1		
Urinary tract inflammation subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Endocrine disorders Endocrine disorders subjects affected / exposed occurrences (all)	0 / 152 (0.00%) 0		
Hypothyroidism			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	4		
Arthralgia			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Arthritis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Fracture pain			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Facial asymmetry			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Musculoskeletal discomfort			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Neck pain			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Osteoarthritis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Osteopenia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Osteoporosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Plantar fasciitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rotator cuff syndrome			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Soft tissue mass			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Spinal deformity			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Spinal instability			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Spinal osteoarthritis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tendonitis			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tenosynovitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	6		
Upper respiratory tract infection			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences (all)	3		
Acute sinusitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Borrelia infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences (all)	2		
Bronchitis viral			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Clostridium difficile colitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Clostridium difficile infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Conjunctivitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Fungal skin infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Diverticulitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gingival abscess			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Herpes virus infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Localised infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Onychomycosis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Otitis externa			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Otitis media acute			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Otitis media chronic			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Periodontitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		

Sinusitis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tooth abscess			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Vaginal infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Diabetes mellitus			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Diabetic metabolic decompensation			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Gout			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hypercholesterolaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hyperlipidaemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		
Polydipsia			
subjects affected / exposed	0 / 152 (0.00%)		
occurrences (all)	0		



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported